SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK: PART 48

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IN RE: OPIOID LITIGATION

INDEX NO.:400000/2017

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September 09, 2020
Central Islip, New York

MINUTES OF FRYE HEARING
(Testimony of Dr. Lembke)

B E F O R E: HON. JERRY GARGUILO
Supreme Court Justice

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STEPHANIE CASAGRANDE, CSR, RPR
OFFICIAL COURT REPORTER

THE CLERK: Supreme Court, State of New York, County of Suffolk, Part 48 is now in session, the Honorable Jerry Garguilo presiding.

THE COURT: Good morning, everybody.

CHORUS: Good morning.

THE CLERK: The case on the calendar is In Re Opioid Litigation, Index Number 400000 of 2017. Your appearances, please, beginning with the Plaintiff.

MR. HANLY: Paul Hanly, for Suffolk County.

MS. CONROY: Jayne Conroy, Suffolk County.

THE COURT: Good morning.

MR. SHKOLNIK: Hunter Shkolnik, Nassau County. Good morning, your Honor.

THE COURT: Good morning.

MS. SALDANA: Lois Saldana, for the New York Attorney General's office.

THE COURT: Good morning.

MS. SALDANA: Good morning.

THE COURT: Anyone else?

MR. BADALA: Good morning, your Honor.

Salvatore Badala, for the Plaintiff.

THE COURT: Good morning.

MR. ASHER: Good morning, Nate Asher, for Janssen Defendants.

MR. SHERIDAN: Tom Sheridan, Suffolk County.

THE COURT: Good morning.

My picture is on the screen. I could do without it. All right. A couple of announcements before we get started.

On Friday we're going to have an abbreviated session. We have our annual 9/11 ceremony, which I will attend. They commence at 3 p.m. on Friday, September 11th, so we'll work somewhat into the lunch hour and recess thereafter, because traditionally that service takes about a little more than an hour.

I received a letter. Apparently, the Plaintiff is not going to call Dr. Keller as an expert; is that correct?

MR. HANLY: That's correct, your Honor.

THE COURT: Okay. So our current schedule will be today, of course,

Dr. Lembke; tomorrow, Dr. Keyes; and on Friday, during the abbreviated session, we'll start with Dr. James Tomarken.

Is everybody on board with that?

MS. WELCH: Donna Welch, for the Allergan Defendants. We are on board with that, but we have sent a proposed Stipulation to the Plaintiffs regarding the withdrawal of Lacey Keller as an expert.

We want to make sure that she is being withdrawn for all purposes from their case in chief. We want to ensure that they are not taking her down from the Frye hearing with any intent to have any other of their experts adopt her opinion in whole or in part or rely on her opinion in whole or in part in their case in chief.

We assume that's the intent here, but we want to make sure of that before we're precluded from an opportunity to engage in a Frye hearing on her opinions.

THE COURT: So, in other words, you want to come to an agreement?

MS. WELCH: Correct, your Honor.

THE COURT: The letter I received indicates that they may call her as a rebuttal witness, and in the event they choose to do so, we would have a limited Frye hearing.

Your issue deals with whether or not any other expert tends to rely on that testimony?

MS. WELCH: Correct, your Honor. Our concern is simply that on the current record, Plaintiffs have relied themselves on Ms. Keller for purposes of summary judgment briefing. If we are withdrawing her -- if they are withdrawing her as an expert, we don't think that's appropriate.

So we believe they shouldn't be able to use her opinions in response to a renewed summary judgment motion, and we want to make clear that their other experts in their case in chief cannot simply rely on her opinions that are being withdrawn, and they can't adopt her opinions as their own.

THE COURT: You said that twice now. Work it out. If you can't work it out, I will.

MS. WELCH: Thank you, your Honor.

MS. CONROY: Thank you, your Honor.

THE COURT: Tech people, I'm hearing myself twice. It's like a network five-second delay. Okay. Call a witness.

MS. STRONG: Your Honor, this is Sabrina Strong, for Johnson & Johnson and Janssen. Before we begin, I'd like to address one issue, your Honor.

THE COURT: Go ahead.

MS. STRONG: Yesterday you received a letter that was filed by some of the Defendants relating to a late disclosure of materials related to Katherine Keyes.

After that, we actually received from Plaintiffs' counsel yesterday, approximately 4:40 p.m., a late disclosed list of supplemental materials for Dr. Lembke, who is scheduled to testify, as you know, this morning.

There is 239 documents identified on that supplemental materials considered list that we received at 4:40 yesterday. I have not even had an opportunity to review them,

let alone determine whether we have access to all those materials.

I understand they include materials from 1995, early 2000, materials that could have been included and considered by her before her deposition, before she submitted her report.

We would ask, your Honor, that they not be permitted to elicit any testimony or any opinions that rely upon those materials or address those materials in any way at the hearing today, your Honor. This is classic sandbagging. The discovery rules do not permit for this, and so we would ask for that relief, your Honor.

MR. HANLY: Your Honor, they've had these materials since August the 3rd when they were disclosed in connection with the West Virginia litigation. So the notion that they're just seeing them for the first time now is simply not true.

The second point is, of course, as your Honor knows, an expert's work, an expert's opinions are not static. They are dynamic,

and they change over time, and many of these materials were created subsequent to Dr. Lembke's deposition in this case. So we really don't think that this is a serious issue.

MS. STRONG: Again, your Honor, I'm not familiar with what has been disclosed in West Virginia and what has not, but to get a list of 239 documents at 4:50 the night before a Frye examination is absolutely improper, your Honor.

New York courts have plainly held that the expert discovery rules are promulgated so that no party will be sandbagged or surprised, and that's plainly what this is.

And I do understand, your Honor, that there are many documents. I don't know the totality because, as I said, I haven't looked at the 239 documents, but I understand that there are many that predate her deposition, long predate her deposition.

THE COURT: Okay. In the event during the course of the examination if, in fact, there is reference to a contested exhibit,

note your objection and I'll rule on it at the time.

Apparently, through the course of these hearings, although hundreds of exhibits have been noted, very few have actually made their way into the record. So stay on your toes.

MS. STRONG: All right. I will, your Honor. I have to tell you it's hard to discern that on the fly with over 700 initially identified by her and another 239, so I'd like to have a standing objection at that point, but we'll try to do our best in that regard.

I don't know if Mr. Pyser or Mr. Carter have additional points they would like to make before we begin.

MR. PYSER: Briefly, your Honor. This is Steve Pyser, for Cardinal Health. Just on the idea that we are aware of these because they were disclosed in the West Virginia litigation, not all Defendants here are in the West Virginia litigation, first of all.

Second, there's an entirely different expert report in the West Virginia

litigation.

So if the idea is that we should expect from this witness what she's testified in West Virginia, that gets to the heart of the problem, which is that she entered a report in this case and should be testifying in line with the report in this case, and because there is a report in West Virginia that says different things, that just can't be bootstrapped into this case because there's a materials considered list submitted at 4:39 p.m. the night before the Frye hearing.

That's just classic sandbagging, and your Honor should strike it.

THE COURT: Okay. So noted. Call a witness. I suggest you stay on your toes also. In the event an exhibit is mentioned that you have a problem with, raise your objection at that point.

And, in any event, you'll have a standing objection as we proceed.

MS. STRONG: Thank you, your Honor.

THE COURT: Call a witness, please.

MR. HANLY: Your Honor, the Plaintiffs

call Dr. Anna Lembke, remotely.

THE COURT: Good morning, Doctor. Doctor, can you hear me? Are you muted? Your lips are moving, but I don't hear anything.

DR. LEMBKE: Yes, I'm muted.

THE COURT: Swear the witness in, please.

THE CLERK: Yes. Can you hear me?

DR. LEMBKE: Yes, I can.

THE CLERK: Please raise your right hand.

(WHEREUPON, Dr. A-N-N-A L-E-M-B-K-E, having first been duly sworn by the Clerk of the Court, testified as follows:)

THE CLERK: Please state your name and address for the record.

THE WITNESS: Anna Lembke, 401 Quarry Road, Stanford, California, 94305.

THE CLERK: Thank you.

THE COURT: And, Dr. Lembke, good morning again. I give all witnesses a few pointers that can expedite these hearings.

Of course you're going to be asked some

questions this morning, and I suggest that you limit your answer to the information sought by the question.

For example, if I were on the witness stand and I was asked on what street do I live, I would simply volunteer the name of the street. I wouldn't give the town, the state or the ZIP code because that information is not sought.

Number 2, although in life it is not polite to commence an answer before a question is complete, because we save time that way; however, as you probably know already, in court we require a complete stenographic record of all the questions and the answers.

So even though you know exactly where a question is going, wait for the question to be complete before you commence your answer.

And, number 3, in the event you hear the word "objection" or anything that sounds like "objection," just stop until you get direction from the Court; fair enough?

THE WITNESS: Yes.

THE COURT: Got it. Good. You may proceed.

MR. HANLY: Thank you, your Honor.

DIRECT EXAMINATION

BY MR. HANLY:

Q. Good morning, Dr. Lembke.

A Good morning.

Q. It's early morning where you are; is that correct?

A Yes, it is.

Q. You are in your offices at Stanford University School of Medicine?

A Yes.

Q. Now, you and I have met before, correct?

A Yes.

Q. I presented you in court before Judge Polster some years ago in connection with the opioid litigation; do you recall that?

A Yes, I do.

Q. All right. Now, just as a road map for where we're gonna go, today we're going to be talking principally about methodology, and in order to start us off on what I hope is the right foot, we're going to put up on the screen the nine

opinions that you intend to testify to as and when this case goes to trial, okay?

A Yes.

Q. Then thereafter, we'll go through your qualifications, we'll go through the methodologies, and hopefully this will all be over in a reasonable period of time; fair enough?

A Yes.

MR. HANLY: All right. Could we put up Slide Number 1, please.

Q. Doctor, can you see Slide Number 1?

A Yes.

Q. All right. And is this a list of the nine opinions that you discuss in your report in this case?

A Yes.

Q. All right. And is there anything about this list which is substantively different from the list of opinions in your report?

A No.

Q. All right. Just to go through them very briefly, and I'm just going to paraphrase, your Opinion Number 1 is going to be that addiction is a chronic illness; Opinion Number 2 that opioid

prescribing grows fourfold starting in the '90s, which increased the supply of deadly opioids; Opinion Number 3 is that the opioid industry misled doctors into believing that opioids are more effective and safer than they really are. You then give some examples there.

Opinion Number 4 is that there's no reliable evidence that opioids work for what's called chronic pain. 5 is the increased supply contributed to more individuals becoming addicted to opioids; 6 is increased supply contributed to more individuals, including newborns, becoming dependent on opioids.

Number 7, increased supply contributed to more diversion of prescription opioids; Number 8, the increased supply of opioids through legal and illegal sources resulted in the opioid epidemic; and Opinion Number 9 is the opioid epidemic would not have occurred without the pharmaceutical opioid industry's misleading promotion of opioids.

Did I read those correctly, paraphrasing in part?

A Yes, you did.

Q. All right. And those are the, in sum

and substance, those are identical to the opinions listed in your report; is that true?

A Yes, that is true.

Q. Okay. You can take that slide down, please.

Okay. Doctor, you are currently Associate Professor and Chief of the Addiction Medicine Dual Diagnosis Clinic. You are Medical Director of Addiction Medicine and Program Director of the Addiction Medicine Fellowship within the Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine; is that true?

A Yes.

Q. Now, in that --

THE COURT: Mr. Hanly, I don't mean to interrupt you. I overlooked placing something on the record.

MR. HANLY: Yes, your Honor.

THE COURT: This applies to everybody here and anyone who may be listening through a live stream. That's the rules of the Chief Judge, Part 29, Section 29(1), the general taking of photographs, films, or videotapes,

or audiotaping, broadcasting or telecasting in a courthouse, including any courtroom -- and just for the record, the Court considers the locations where this is being live streamed to be part of our courtroom -- office or hallway thereof, at any time or at any occasion, whether or not the Court is in session, is forbidden, unless permission of the Chief Administrator of the courts or a designee of the Chief Administrator is obtained.

So you may observe the proceedings, but you may not record them, take photographic images, et cetera. Okay. Thank you. I'm sorry, sir.

MR. HANLY: May I proceed, your Honor?

BY MR. HANLY:

Q. Dr. Lembke, among your titles is the Chief of Addiction Medicine within the Dual, dual as in two, Diagnosis Clinic, true?

A Yes.

Q. And in that context, dual diagnosis refers to a psychiatric condition on the one hand, and a substance use disorder on the other, true?

A That is true, yes.

Q. All right. Now, you've been on the faculty at Stanford University School of Medicine since approximately 2003?

A Yes.

Q. All right. And in terms of your background, you did your undergraduate work at an obscure university called Yale?

A Yes.

Q. And you did your medical degree at Stanford University, correct?

A Yes.

Q. You did a partial residency in pathology at Stanford, true?

A Yes.

Q. And following that, a full residency in psychiatry at Stanford?

A Yes.

Q. And following that, a fellowship in mood disorders within the Department of Psychiatry and Behavioral Sciences, true?

A Yes.

Q. You are licensed to practice medicine in the state of California --

A Yes.

Q. -- since 1995?

A Yes.

Q. You actually received a waiver from the Drug Enforcement Administration to prescribe buprenorphine products, true?

A Yes.

Q. And what, what is the circumstance under which you would prescribe buprenorphine, and you do prescribe buprenorphine products?

A I prescribe buprenorphine for patients who have opioid use disorder, a term for opioid addiction, as well as for some patients with severe opioid dependence.

Q. Buprenorphine is itself an opioid product, true?

A Yes, it is.

Q. You're Board Certified, true?

A Yes.

Q. In psychiatry and neurology?

A Yes.

Q. And you are also Board Certified by the American Board of Addiction Medicine; is that true?

A Yes.

Q. And I'm sure Justice Garguilo knows what Board Certified means, but essentially it means that peers within the same area of work as you come together and vote to give you or not give you a certificate demonstrating your expertise in the particular area; is that a fair description?

A Well, it's not really a vote by peers. It's -- you have to complete additional training to get expertise in a certain area. And then typically you have to sit for and pass a board exam.

Q. Okay. But there is a board that actually certifies, true?

A Yes.

Q. All right. Now, you teach medical students at Stanford; isn't that right?

A Yes.

Q. And you've been doing so for nearly 20 years?

A That's correct.

Q. And you've been recognized for your excellence in teaching on two occasions; is that true?

A Yes.

Q. You also maintain an active clinical

practice, true?

A Yes.

Q. And in your clinical practice, a significant portion of your students are -- sorry -- of your patients are patients who have been taking prescription opioids for pain relief and have developed some sort of a use disorder; is that true?

A Yes.

Q. And how many such patients would you say you have treated in the last 20 years or so that you've been treating them?

A Well, I haven't kept count, but it's certainly scores of patients over many years.

Q. Scores did you say?

A Yes.

Q. All right. Now, we're going to hear a bit about some terms that you are very familiar with, but perhaps the Court and others are not.

Can you just briefly explain to the Court what is meant in the context of addiction medicine by the term misuse.

A In the context of addiction medicine, misuse means taking a prescribed medication in a way other than intended by the doctor who prescribed it.

Q. Okay. And how about --

A That's a very broad definition.

Q. That's all --

A Not specific, but...

Q. Thank you, Doctor. That's all I'm asking is a very broad and brief definition so we can orient the Court in terms of your further examination, okay?

A Yes.

Q. And the term "dependence," what does that mean in the context of addiction medicine?

A That refers to patients specifically with opioid dependence for first the patients who have been taking opioids daily for long periods of time who physiologically adapt to the presence of the molecule such that if they reduce their dose or stop it altogether, they experience opioid withdrawal.

Q. And the term "addiction," how is that term used in your field?

A So addiction is a complex biopsychosocial disease that can broadly be defined as the continued compulsive use of a substance despite harm to self and/or others.

Q. And without getting too technical, is there a relationship between that term addiction that you've just defined and something called opioid use disorder, O-U-D?

A Yes. So opioid use disorder is the terminology used in the Diagnostic and Statistical Manual of Mental Disorders in the latest edition, and it's essentially synonymous with addiction.

Q. Now, in working with the patients in your clinic, you develop treatment plans to deal with opioid use disorder, or addiction, or dependence, or misuse?

A Yes.

Q. And those treatment plans can include nonopioid medications, true?

A Yes.

Q. Also nondrug plans of rehabilitation, if you will?

A Yes, correct.

Q. Now, you also hold a position in the Stanford Department of Anesthesiology and Pain Medicine, true?

A Yes. I have a courtesy appointment in anesthesiology and pain medicine.

Q. And the courtesy appointment does, however, enable you to treat pain patients, correct?

A Yes.

Q. Now, over the years of your career, is there a body of scientific and medical literature that you have studied to understand the relationship among pain, dependence, and addiction?

A Yes.

Q. And have you personally contributed to that body of literature?

A Yes, I have.

Q. Have you written peer -- what are called peer-reviewed papers in that area?

A Yes.

Q. For the record, peer-review refers to the process by which an author submits her manuscript to a particular scientific journal or journals, and the journal then sends the paper to other experts in the field to determine whether the paper is worthy of publication in that particular journal. Is that a fair description of peer-review?

A Yes.

Q. Now, in addition to peer-reviewed papers, you've also written a book concerning

opioids and addiction, true?

A Yes.

Q. And I'm holding up -- can you actually see me, Doctor?

A Yes, yes, I can.

Q. So I'm holding up rather awkwardly a book that you have published called Drug Dealer M.D. That is your book, correct?

A That's correct.

Q. Okay. And this book was published in 2016, true?

A Yes.

Q. And 2016 was prior to the time that you first came to work with lawyers in connection with the opioid litigation, true?

A Yes.

Q. Your book was published, for example, before you and I even met, true?

A Yes.

Q. Now, has this book received some positive press, if you will?

A Yes.

Q. And, in fact, the New York Times selected it as one of the top five books to read if

you wish to understand the opioid epidemic and how we got to where we are today, true?

A Yes.

Q. Now, you began to treat patients with substance abuse issues in the late 1990s, true?

A That's correct.

Q. And the substances that your patients were abusing included prescription painkillers, true?

A Yes.

Q. Prescription benzodiazepines?

A Yes.

Q. Alcohol, true?

A Yes.

Q. Tobacco?

A Yes.

Q. Marijuana?

A Yes.

Q. A panoply of addictive substances, true?

A That's correct.

Q. Now, had some of those patients that you treated received opioid prescriptions from their own doctors?

A Yes. The majority.

Q. And they presented to you with some sort of a substance use disorder; is that true?

A That's right.

Q. Following the lawful prescription to them by their own physicians, true?

A That's correct.

Q. Did the book that you published include any information about prescription opioid deaths among New York Medicaid patients?

A Yes, it did.

Q. And do you recall what your research showed about New York Medicaid patients who had been prescribed opioids?

A It showed that New York Medicaid patients are more likely to be prescribed an opioid than the non-Medicaid patients and more likely to die of an opioid overdose.

Q. Now, is reading the medical literature, a literature written by persons other than yourself, is that a standard part of your practice as a doctor and as a professor at Stanford University?

A Yes, it is.

Q. Why is that? Why is that a standard methodology in your work?

A I need to read the medical literature to stay up to date on the science, and to take good care of my patients, and also to teach medical students, Stanford undergraduates and physicians in training, residents and fellows.

Q. Let me ask you about those students.

Do you develop a curriculum for those students?

A Yes.

Q. Is there any relationship between the curriculum that you develop and the medical literature written by persons other than yourself?

A My curriculum is formed by my review of the best evidence in the medical literature.

Q. All right. Now, in addition to the work you've described thus far, were you ever appointed to any panels within the state of California dealing with opioid misuse?

A Yes. I was appointed to the research advisory panel of California by Governor Jerry Brown.

Q. And what was the upshot of that panel?

A Our role was mainly to assist the safety of clinical trials being conducted in the State of

California.

Q. Now, you used the term "safety." That's a term that we hear a lot of in the context of prescription medications, true?

A Yes.

Q. Safety and efficacy are two interrelated concepts in the pharmaceutical world, true?

A Yes.

Q. And those are, those are two concepts that the FDA pays particular attention to in respect to prescription medications, true?

A Yes.

Q. Do safety and efficacy relate to something called a risk-benefit profile?

A Yes.

Q. And just very briefly describe for Justice Garguilo what that risk-benefit profile is in the context of opioids.

A So with opioids, it's just essential to assess whether or not the safety of the opioid in a given patient is -- whether or not the benefits in that patient outweigh any risks or unintended adverse medical consequences.

Q. Okay. Is it fair to say that safety and

efficacy are key concepts in the context of prescription medications?

A Yes.

Q. And in the context of prescription opioid medications?

A Yes.

Q. Now, in reaching the conclusions that are discussed throughout your book published in 2016, did you apply the same methodology in reaching those conclusions that you use in your professional work as a scientific researcher and a medical doctor?

A Yes, I did.

Q. And let me ask you this: Are you familiar with something known as a pharmaceutical sales representative detailing?

A I'm sorry, I didn't catch the last word.

Q. Are you familiar with something known as pharmaceutical sales representative detailing?

A Yes, I am.

Q. All right. And is it fair to say that that's the circumstance where a pharmaceutical company sales representative goes into a doctor's offices or other healthcare provider's offices and

discusses, presents to the healthcare provider purported information about particular drugs?

A Yes, that's correct.

Q. Now, in writing your book, did you -- did you have regard to any information concerning sales representative representations about opioids made to healthcare providers?

A Yes.

Q. You had access to materials in the public domain concerning the kinds of statements and documents that were being provided by sales representatives, opioid sales representatives to healthcare providers?

A Yes.

Q. These were documents that predated the documents you received from the lawyers in connection with the various opioid litigations, true?

A Yes.

Q. Okay. Now, since you were -- began to do some work for the lawyers in the opioid litigations, you were provided with internal company documents concerning those promotional messages, true?

A That is correct.

Q. And you reviewed all of that material?

A Yes.

Q. And did you reach conclusions concerning the truth or falsity of those messages?

A Yes, we did.

Q. In reaching those conclusions, did you use the same methodology you have used historically as a scientific researcher and a medical doctor in the sphere of addiction medicine?

A Yes.

Q. That methodology, that series of steps didn't change in any way as between pre litigation, for example, and the work you've done in the litigation?

A No, it did not change.

Q. Okay. Now, have you undertaken any sort of a program designed to correct any misrepresentations that pharmaceutical sales representatives made to healthcare providers in the United States?

A Yes.

Q. And do you call that program academic detailing in contrast to pharmaceutical sales rep

detailing?

A Yes, I do.

Q. And in the course of -- and the nature of that academic detailing program that you, that you engage in, you actually go around the country from time to time and provide lectures and other support to healthcare providers to deal with the potential misinformation they may have received from the drug companies, true?

A Yes.

Q. And you've actually done this academic detailing, among other places, right here in the State of New York, true?

A Yes.

Q. And you've received thanks from the various healthcare providers for presenting this information correcting misinformation; is that correct?

A Yes.

Q. You've been invited to many different conferences and speaking opportunities throughout the United States to provide this academic detailing, true?

A Yes.

Q. And do you continue to do that work today?

A Yes, I do.

Q. And how many such talks, presentations, meetings would you say you've had since the publication of your book in 2016?

A I've had over 100 live speaking engagements since the publication of my book in 2016.

Q. Okay. I want to turn now to -- among your peer-reviewed materials, you published a research letter that looked at the patterns of opioid prescribing under the federal Medicare program; is that true?

A Yes.

Q. And what you want to look at was how many scripts are being written for Medicare beneficiaries over any particular period of time, correct?

A That's correct.

Q. And tell Justice Garguilo what your work discovered concerning prescribing under the Medicare program.

A We found that over one-third of Medicare

Part D patients is prescribed an opioid in any given year.

Q. In addition to what we've already discussed, have you provided any other public health service, such as consultation with any congressional bodies or with the White House?

A Yes.

Q. Just very briefly, what did you do in that context?

A I testified before lawmakers in Washington regarding opioid safety and efficacy of opioids. I've been to White House meetings convened to address how to target and abate the opioid epidemic.

I've talked with governors and other lawmakers in states across the country regarding the opioid problem.

Q. Okay. Now I want to turn to discuss a bit with you the methodology that underlies the actual opinions in this case, okay?

A Yes.

Q. All right. Now, you already testified that in, that in writing your book, you used the same series of steps, methodology that you use in

your, in your scientific work and in your clinical practice, correct?

A Yes.

Q. And in reaching the opinion which we saw in Slide Number 1 of the nine opinions in this case, you reviewed scientific and medical literature concerning opioid papers that were written by folks other than you, correct?

A Yes.

Q. And how many such papers in connection with this litigation -- and by "this litigation," I mean not only this case, but the other cases in which you've been engaged -- would you say you looked at concerning opioids?

A I've reviewed over 600 papers regarding opioids in the medical literature for this litigation.

Q. Okay. Now, when you say you reviewed the 600 or so papers, let me ask you, first of all, all of these papers or virtually all of these papers, they have at the front something that's called an abstract, right?

A Yes.

Q. And that's like a little summary of what

the whole paper is gonna be about, correct?

A Yes.

Q. So in looking at the 600 papers, did you just take a look at the abstract and move on?

A No. My methodology is founded in in-depth analysis of these papers in order to determine whether or not the information in the abstract summary is reflected in the rest of the paper and supported by the data that the authors put forth.

I'm also very careful to look at things, like any conflicts of interest that the authors may have and also who funded the study.

Q. Well, let me see if I understand this.

Are you saying that the abstract, which summarizes the paper, in some instances might not be accurate as a summary?

A I'm saying that the abstract, in my research, has shown that an abstract doesn't necessarily reflect the true state of the data that the authors put forth, nor does it necessarily reflect an appropriate summative conclusion derived from the data, which is relevant because most healthcare providers, busy clinicians almost always

-- I won't say almost always, but very often just read the abstract.

Q. So do I gather from your answer, Doctor, that in reviewing the 600 papers in connection with the opioid litigation, you actually read every page of every study?

A Yes.

Q. So we have an example of what you just testified to. Could we put up Slide Number 2, please.

Doctor, can you see that slide?

A Yes, I can.

Q. Now, correct me if I'm wrong, this is a part, a pullout, if you will, from a paper by a Dr. Chou, C-H-O-U, that you reviewed as part of your work in connection with this case, correct?

A That's correct. It's by a large number of authors. Dr. Chou is the first author.

Q. Correct. And so what we're seeing here is we've pulled out the abstract, and you've actually highlighted a part of the abstract that reads: "Chronic opioid therapy can be an effective therapy for carefully selected and monitored patients with chronic non-cancer pain."

Do you see that?

A Yes.

Q. And why did you highlight that as part of your testimony here today?

A I highlighted that because that statement is not reflective of the evidence, and I think it would be misleading for many readers if they only read the abstract.

Furthermore, the recommendations of the authors are -- and I highlighted the strong recommendation for the use of chronic opioid therapy in the treatment of chronic non-cancer pain, which they then briefly qualify with the words "low quality evidence," which is strange that they would have a strong recommendation for a treatment that has low quality evidence.

Furthermore, reading more in depth, it becomes evident that the authors themselves know that the evidence is insufficient, the evidence for the use of opioids in treatment of chronic non-cancer pain is insufficient to assess the effects on health outcomes, which is that third box pulled out below.

It's also worth mentioning that that low

quality information is in an appendix of the article. So you really have to go digging for it.

THE COURT: Excuse me. Doctor, who prepares the abstract, the author or someone else?

THE WITNESS: The abstract is prepared by the authors.

THE COURT: Okay. Thank you.

BY MR. HANLY:

Q. And, Doctor, essentially what you are calling out is the inconsistency between the sentence in the abstract that says: "Chronic opioid therapy can be effective," and the sentence at the very bottom that says: "Evidence is insufficient to assess effects on health outcomes," true? That stuff --

A Yes. Yes. And this is a pattern that repeats itself throughout the medical literature when looking at the data on opioid use for chronic pain.

Q. Now, there's something else about this paper, is there not, that caught your attention? Could we have Slide Number 3, please.

And this is from the appendix. It's a

little hard to read, but this is the list of panel members who participated in the promulgation of this paper, true?

A Yes. So it is standards that all authors who publish in peer-reviewed journals must declare their financial conflicts of interest.

And what's notable here is that more than half of the authors in this 2009 publication who strongly recommended the use of opioids in the treatment of chronic pain, despite weak and insufficient evidence, were, in fact, receiving financial fees, consultative fees from the opioid industry.

Q. Okay. And, in fact, we see here under Dr. Perry Fine, he discloses that he serves on advisory boards for a number of different companies, including Johnson & Johnson, Purdue Pharma and Endo. Do you see that?

A Yes.

THE COURT: Apparently -- correct me if I'm wrong -- Dr. Fine and Dr. Portenoy appear in the original, in the original Complaint --

MR. HANLY: Precisely, your Honor.

THE COURT: -- as Defendants.

MR. HANLY: As Defendants, that's correct.

BY MR. HANLY:

Q. And as the Court already noted, we have Dr. Portenoy there in the box below, and Dr. Portenoy discloses consulting agreements with an extensive list of pharmaceutical companies estimated to work with four to five within a three-year period, et cetera, correct?

A Yes.

Q. And is this in-depth analysis of scientific literature published by folks other than yourself, is that a standard method in order to reach conclusions about, for example, the effectiveness of opioids for chronic pain?

A Yes.

Q. And is that the methodology that you followed as part of getting to your opinions in this case and your opinions in your pre litigation book?

A Yes.

Q. Now, in looking at these 600 papers that you looked at -- I'm finished with that slide. Thank you.

In selecting the papers to review, the

600 or so, did you exclude papers that contained views that disagreed with yours?

A No.

Q. Why did you include papers which disagreed with yours as part of your methodology?

A Well, those are the papers that would be important for me to look at even more closely to understand how those authors came to conclusions that seem to be going in a direction different from the conclusions that I'm deriving from the evidence.

Q. All right. Now, did you review something that's become known, become legendary, if you will, in this litigation called the Porter and Jick letter?

A Yes.

MR. HANLY: Could we put up Slide Number 4, please.

BY MR. HANLY:

Q. Now, Doctor, can you see that screen?

A Yes, I can.

Q. This is the entirety of the Porter and Jick paper, true?

A Yes. I wouldn't even call it a paper. It's a letter to the editor.

Q. Right. It's an 11-line, five-sentence letter to the editor from the New England Journal of Medicine in 1980 that essentially was a review of some 12,000 patient hospital charts to see whether in those charts the healthcare provider had noted any signs of addiction to the narcotic drugs that had been administered to those 12,000 patients, correct?

A Yes.

Q. This letter has been cited close to a thousand times in the medical literature since 1980, true?

A Yes.

Q. This letter was used by the pharmaceutical opioid manufacturers to support the idea that addiction in patients taking opioids was extremely rare, true?

MS. STRONG: Objection, your Honor.

THE COURT: There's an objection. What's the nature of the objection?

MS. STRONG: Your Honor, it's leading. I know we're being very lenient with leading, but when it comes to feeding the expert substantive components of the opinion, I

would ask that they not lead, your Honor.

THE COURT: I agree. Rephrase the question.

MR. HANLY: Sure thing.

BY MR. HANLY:

Q. Dr. Lembke, employing your usual methodology for examining a scientific publication, did you use that methodology in connection with this letter to the editor?

A Yes.

Q. And can you tell the Court what history teaches happened after the publication of this letter?

A Well, I think it's important to note, first, that in my review of the medical literature, I saw this article frequently cited. I also saw it cited in promotional material from the opioid industry.

But what's important to note about this data point is that it's a very low quality piece of evidence. It's not purely a peer-reviewed paper. It's a letter to the editor. It's not representative of the types of patients who are -- have become dependent on and addicted to opioids in

the United States today.

These are hospitalized patients, many of who received a single dose of an opioid administered by a healthcare provider. This is not a reliable piece of evidence to consider the risk of addiction in ambulatory outpatients receiving opioids in large quantities for long duration.

Nonetheless, this paper had a huge influence on opioid prescribing and the healthcare perspective on the safety of opioids in the treatment of pain, such that it contributed to an increase in opioid prescribing.

MR. HANLY: Thank you, Doctor.

You can take that slide down now, please.

BY MR. HANLY:

Q. Now, during the course of your work in this case, Doctor, we've already established that you looked at certain materials provided to you by the Plaintiffs' lawyers from the Defendants internal files concerning statements about the safety and efficacy of opioids, true?

A Yes.

Q. And did you, as part of your work in

this case, did you compare those documents, the statements in those documents with the medical literature to see whether the statements made by the manufacturers were consistent with the medical literature?

A Yes, I did.

Q. And what did you, as part of your methodology, what did you discover?

A I discovered that there were many inconsistencies in terms of what the promotional material was saying about the safety and efficacy and what the evidence was saying about safety and efficacy.

Q. Now, in addition to your review of the published medical literature by doctors other than yourself, did you, in forming your opinions in this case, did you rely on your clinical experience treating patients with pain and substance use issues?

A Yes.

Q. And can you just briefly explain how your personal professional experience figured into the methodology that underlies the opinions you give -- you intend to give, with the Court's permission,

in this case?

A So I observed thousands of patients over the past 20 years becoming addicted to prescription opioids, and I went to the medical literature to see whether or not there was evidence to support my clinical experience, whether my clinical experience was not based in evidence. And when my clinical experience seemed to be divergent from the evidence, I tried to figure out what I might be missing in terms of my clinical impression.

So the medical science was very important, touchstone in terms of evaluating my clinical experience.

Q. Okay. You used the term evidence a couple of times in your answer and his Honor, I believe, has heard of the concept of evidence-based medicine. Is that a concept you're familiar with?

A Yes, it is.

Q. And, very briefly, what does that concept connote?

A Evidence-based medicine speaks to the idea that when we ground medical practice in science we will have better medical care. So it's important to, you know, clinical experience is important, but

it's important to reflect on our clinical experience in the context of the scientific evidence.

Q. And do you, as part of your methodology in this case, did you -- did you employ evidence-based medicine?

A Yes.

Q. Now, let me ask you, in applying your methodology to reach your opinions in this case, did you determine whether you were able to state those opinions to a reasonable degree of scientific and medical certainty?

A Yes.

Q. And are you?

A Yes.

Q. Now, let's talk about some basic terms. Then we'll go through this section quickly, but just so that we have for the record, let's start with the basics. Just tell the Court very briefly what opioids are.

A So opioids are molecules that bind to opioid receptors in the brain, and they have very powerful effects. They can relieve pain in the short-term.

They also stimulate a part of the brain

called the dopamine reward pathway, which is why they are highly addictive. And they also work on a part of the brain called the brain stem, which controls the breathing rate, and they can slow -- powerfully slow down the breathing rate and the heart rate, which is why they're very, very lethal and why people overdose and die from them.

Q. All right. Now, the first opinion of your nine opinions on the list relates to addiction to opioids, correct?

A Yes.

Q. And you state in that opinion that addiction, addiction is a chronic illness. So staying with the basics, there are accepted definitions of addiction within the area of addiction medicine, true?

A Yes.

MR. HANLY: All right. Can we put up Slide Number 5, please.

BY MR. HANLY:

Q. And while we're doing that, I will ask the Doctor, is there a body called the American Society of Addiction Medicine?

A Yes.

Q. And is that a body that you are, in some fashion, a member of?

A Yes.

Q. And that's a body that is interested in issues surrounding addiction, true?

A Yes. It's a professional medical society for healthcare providers who treat and research addiction.

Q. Okay. And the American Society of Addiction Medicine came up with this definition of addiction which reads: Addiction is a treatable, chronic medical disease involving complex interactions, paraphrasing, and an individual's life experiences.

People with addiction use substances -- or -- use substances. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.

Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.

Did I read that correctly?

A Yes.

Q. Okay. And is this definition by the American Society of Addiction Medicine, is that some sort of an outlier?

A No. That's a well-accepted definition of addiction medicine, addiction in the field.

Q. All right. It's regarded as a -- strike that.

Did this definition, promulgated by this Society of Addiction Medicine, result from some sort of a consensus of experts in the field?

A Yes.

MR. HANLY: Thank you. I'm finished with that.

BY MR. HANLY:

Q. Now, there's -- just anticipating potential questions from the esteemed lawyers for the drug companies, there's another organization called the American Psychiatric Association, which has a slightly different definition of addiction, true?

A Yes. You're speaking of the Diagnostic and Statistical Manual of Mental Disorders?

Q. Yes. What's called the DSM.

And the DSM, which is a publication of

the American Psychiatric Association, it uses the term -- instead of addiction, it uses the term opioid use disorder, true?

A Yes.

Q. The Judge has heard that from prior testimony, sometimes called OUD, true?

A Yes. I don't know what the Judge has heard before, but, yes.

Q. Okay. If you accept that, I think we'll be okay.

Now, is there, based on your review of the medical literature concerning addiction and your 20 years or so --

A I'm sorry, I can't hear you when you walk away from the microphone. I'm sorry.

Q. I'm sorry. Based upon your experience as a scientist and a doctor engaged in these -- the area of addiction medicine, is there any real difference between the definitions of addiction that the American Society came out with and the definition of opioid use disorder that the American Psychiatric Association has adopted?

A No. In essence, they're saying the same thing.

Q. Okay. Now, in your Opinion Number 2 in this case, which is part of Slide Number 1, but we don't need to put it up, you state: Opioid prescribing grows fourfold starting in the 1990s, which increased the supply of potent and deadly opioids, et cetera, including in New York, correct?

A Yes.

Q. And elsewhere you've written of what you call a paradigm shift in the prescribing by doctors of opioids beginning in the 1990s, true?

A Yes.

Q. So what happened in the 1990s that was different from what happened over the decades prior to the 1990s in connection with physicians' prescribing habits for opioids?

A Yes, so this was a shift that really began in the 1980s with the advent of the hospice movement and then really gained momentum in the 1990s, but the shift was essentially the following:

Prior to 1980 doctors were very reluctant to prescribe opioids for their patients because they were concerned that their patients would get addicted.

This was based on historical prior

doctor-caused opioid epidemic back -- dating back at least to the Civil War, early 1900s. But in the 1990s there was a huge change in the way that doctors were trained to regard opioids.

They were taught that opioids -- that the risk of addiction to opioids are -- is very, very small, as long as the opioids are being prescribed by a doctor for a patient with real pain and real disease, that somehow that prescription pad could confer some kind of halo effect, and the fact that the patient had serious pain would protect them from addiction.

Doctors were also taught that opioids are effective treatment for chronic pain and that you can continue to go up on the dose without endangering a patient.

So these were huge changes in the way that opioids came to be used, and the treatment really began in medical school.

I went to medical school in the 1990s, and I was the recipient of this training.

Q. And what you just described, Doctor, is there any historical evidence to support what you just said, for example, in the literature?

A Yes. So there are studies, peer-reviewed literature showing that the risk of addiction is quite common, even among patients who are prescribed opioids by a doctor for pain. And those data points predate this paradigm shift that occurred in the 1990s.

So the bottom line is we, as a healthcare institution, knew that this risk was there, and then we collectively forgot it for about two or three decades.

Q. Your Opinion Number 2 that we've been talking about, this increase of prescribing, fourfold increase, four times what had been prescribed earlier, is there, is there any consensus in the areas of addiction medicine as to whether this increase resulted in any increase in unfavorable outcomes for the patients?

THE COURT: Just yes or no. Just yes or no, Doctor.

A Yes.

MR. HANLY: All right. And could we put up Slide Number 6.

BY MR. HANLY:

Q. And let me ask you, Doctor, is there, is

there data from the Centers for Disease Control concerning the increase of prescriptions along with potentially adverse events?

A Yes.

Q. And please describe for Justice Garguilo what is, what is shown here in this, in this graph with the three lines going from left to right.

A This graph shows that as the sales of prescription opioids increased between 1999 and 2010, so did opioid-related overdose deaths, as well as the number of people presenting to addiction treatment centers with opioid addiction.

Q. Okay. So, just for the record, the green line, which is at the top, reflects sales; is that correct?

A Yes.

Q. Of prescription opioids, yes?

A Yes. Yes, it does.

Q. And the middle line is showing overdose deaths; is that right, Doctor?

A Yes, that's correct.

Q. And the bottom line, the orange line is showing treatment admissions for folks suffering from opioid use disorder, true?

A True.

Q. Okay. Now -- and this, is this CDC data generally accepted by folks in the addiction medicine area as being reliable?

A Yes.

Q. Did you -- did you use this as part of your methodology in reaching your Opinion Number 2 in this case?

A Yes.

Q. Okay. Now, did this phenomenon of the fourfold -- you can take that down, slide down, please.

Did this phenomenon that you've described as a fourfold increase in prescriptions, did this happen also in the State of New York?

A Yes, it did.

MR. HANLY: Could we have Slide Number 7, please.

BY MR. HANLY:

Q. Now, Slide Number 7 is titled, Amount of Opioids Prescribed in State of New York between 1997 and 2016, almost a 20-year period, true?

A Yes.

Q. And I'm sure Justice Garguilo -- I hope

Justice Garguilo can see this, but just explain, very briefly, what do we see here?

A Well, what we see here is that in 1997, 100 morphine milligram equivalent was prescribed per person in the State of New York, and between 1997 and 2016 that increased almost fivefold.

MR. HANLY: Okay. Thank you. You can take that slide down.

BY MR. HANLY:

Q. Now, Doctor, I want to talk a little bit briefly, I hope, about the methodology and the bases for your Opinion Number 3 in this case, which is that the opioid industry misled doctors into believing that opioids are more effective, et cetera, okay?

A Yes.

Q. And I noticed that part of the subtitle of your book, Drug Dealer M.D., is how doctors were duped, correct?

A Yes.

Q. And can you explain to the Court what you meant by that, that the doctors were duped?

A The doctors were duped by the pharmaceutical opioid industry into believing that

opioids are safer than they really are and more effective than they really are.

Q. Okay. And in the book you talk about --

MR. PYSER: Your Honor, this is Steven Pyser for Cardinal Health. I'm just going to register an objection and apologies for the late objection.

Vague on the question, the meaning of what the pharmaceutical opioid industry is here. That's not a term that really has a definition, and as distributors, we don't believe that to be a part of anything.

I think the testimony needs to be more specific.

THE COURT: I think the doctor is basically testifying to her findings and impressions, of course, subject to your cross-examination. Am I missing the point of your objection? If I am, tell me.

MR. PYSER: Yeah, just, your Honor, that the term is vague. What this pharmaceutical opioid industry is is not defined, and it's being used in a way that is very unclear through the testimony.

THE COURT: Mr. Hanly, develop that record.

MR. HANLY: I can rephrase, your Honor.

THE COURT: Rephrase it.

BY MR. HANLY:

Q. Doctor, in your book you discuss the alleged fact that certain companies engaged in the manufacture of opioids created a false narrative; is that fair?

A Yes.

Q. Okay. And you -- and you've already explained what you meant by that part of the subtitle that says that the doctors were duped, okay?

A Yes.

Q. Okay. Now, in your book you talk about certain myths that certain opioid-related companies promulgated, correct?

A Yes.

MR. HANLY: Okay. And let's take a look at an example of a piece of marketing material that, that we have as Slide Number 8. Could we put up Slide Number 8, please.

BY MR. HANLY:

Q. Doctor, Slide Number 8 is actually a page within a marketing brochure that was distributed under the auspices of something called the American Academy of Pain Medicine. Do I have that organization correct?

A Yes. That was not the only organization that was involved, but yes.

Q. Okay. This also was a piece of marketing material that was used and disseminated by a company called Janssen; is that correct?

A Yes. This was promoted as an educational booklet.

Q. Okay. And so this is the authors of this piece saying that, Number 1, it is a myth that opioid medications are always addictive and that the true fact, appearing right there, is that many studies show that opioids are rarely -- and they emphasize the word rarely -- addictive when used properly for the management of chronic pain, correct?

A Yes, that's correct. That's what it says.

Q. Right. And as part of your opinions in this case, you came to the conclusion that that

so-called fact is, in fact, a falsehood?

A Yes.

Q. And explain why it's false.

A Their use of the term rarely addictive is not based on science. What we see is that between 10 percent and 30 percent of patients prescribed an opioid by a doctor for chronic pain will develop some kind of opioid use disorder.

Q. Okay.

A And, furthermore, this was known prior to the publication of this so-called educational pamphlet.

Q. Okay. And the second myth that the certain companies engaged in opioid manufacture said was, in fact, a myth is that opioids make it harder to function normally, and what the pamphlet says is, no, that's not correct. When used correctly for appropriate conditions, opioids may make it easier for people to live normally. That's what the answer is supposed to be, right?

A Yes.

Q. And is that answer based upon the use of your methodology reviewing 600 articles and your 20-odd years of clinical practice; is that a true

statement?

A No.

Q. Okay. And then the last so-called myth that the certain of these companies supported is that opioid doses have to get bigger over time because the body gets used to them, and they say, well, that's not true. The true fact is that unless the underlying cause of your pain gets worse, such as with cancer or arthritis, you will probably remain on the same dose or need only small increases over time.

Is that alleged fact true or false based upon your methodology in this case?

A That is false.

MR. HANLY: Now -- your Honor, did you want to take a break at this point?

THE COURT: Talk to my stenographer, when her fingers get tired.

MR. HANLY: I'm flying along.

THE COURT: As a matter of fact, she's getting a note right now from me telling me to give me a heads-up when she needs a break.

MR. HANLY: Okay. I just want to make sure I'm doing what the Court wants.

BY MR. HANLY:

Q. All right. Now, Doctor, we actually created a slide that contains Dr. Lembke's myths about opioids, true?

A Yes.

MR. HANLY: Could we have Slide Number 9, please.

BY MR. HANLY:

Q. And what you created here is, in part, contradicts what we just saw from certain opioid-related companies, correct?

A Yes.

Q. And we've already gone over this, but very quickly, you say that it's a myth that the risk of addiction is rare. You say it's a myth that opioids are effective in treating chronic pain. You say it's a myth that no dose is too high. And you say it's a myth of a concept called pseudoaddiction which, am I correct, is the notion that if you're craving more of the drug, you may not -- that may not be addiction at all but simply your body crying out for pain relief; is that correct?

A Yes. I think pseudoaddiction means that if you're manifesting many of the signs and symptoms

of addiction, you're not really addicted, you're in pain, and the solution is to give more opioids.

Q. Okay. And we've already established what you did in terms of your methodology with respect to Myth Number 1, that becoming addictive -- addicted is rare.

With respect to Myth Number 2, that opioids are effective in treating chronic pain, just very briefly, was the methodology any different that you employed?

A No.

Q. And how about with respect to your claim here that it's a myth that no dose is too high; did you employ that same methodology?

A Yes.

Q. Did you look at -- did you look at scientific papers published by people other than you?

A Yes.

Q. Okay. And the same with respect to Myth Number 4, any difference in the methodology that you used?

A No.

Q. Basically two components of your

methodology, is that correct, your review, in-depth review of the substantial body of medical literature taken together with your, what I'll call your personal professional experience, meaning your clinical practice and your interaction with other healthcare providers; is that fair?

A Yes.

Q. Now, let's, let's look at Slide Number 10, please, and tell Justice Garguilo, this is headed, Prescription Opioids are as Addictive as Heroin. That's rather a strong statement; isn't it, Doctor?

A Yes, it is.

Q. And tell Justice Garguilo what we've done here. We've pulled out these two, two quotations, quotations from a medical paper by an author named Harbaugh that appeared in the Journal of Pediatrics in 2018. So what is the point of this -- these quotes?

A There is consensus in the medical profession that heroin is -- that prescription opioids, Schedule II prescription opioids are as addictive as heroin, that there's really no difference between heroin and prescribed opioids for

pain.

Q. By the way, is the Journal of Pediatrics based on your work in researching medical journals; is that a peer-reviewed journal?

A Yes, it is.

Q. Does it have -- is it regarded as reputable?

A Yes, it is.

Q. Now, let's next look at Slide Number 11, which relates to your Opinion Number 4, and this, this is Opinion Number 4, the heading, There is no reliable evidence that opioids work for chronic pain. And in reaching that conclusion, what did you do?

A I reviewed many, many articles, clinical trials, observational studies, epidemiologic studies looking at whether or not long-term opioid therapy is effective in the treatment of chronic pain.

Q. And is this an article that you looked at?

A Yes.

Q. Is -- and the journal is called Pain?

A Yes.

Q. Is that a peer-reviewed paper?

A Yes.

Q. Is it the only paper that you relied upon in reaching your conclusion that there's no reliable evidence that opioids work for chronic pain?

A No.

MR. HANLY: Okay. Sorry, your Honor. I just lost my track.

Could we put up Slide Number 12, please.

MS. STRONG: Your Honor, objection. This is Sabrina Strong for Johnson & Johnson. This is one of those documents, it appears, your Honor, where they're relying upon something that was submitted to us for the first time yesterday at 4:40 p.m. from their supplemental material considered list, and we would object to any questions relating to this document on this slide on that basis, your Honor.

THE COURT: Mr. Hanly.

MR. HANLY: Again, your Honor, Ms. Strong is a leading member of the national defense team, and in that capacity, she would have had access to the supplemental

materials provided on August the 3rd in connection with the West Virginia cases.

THE COURT: Ms. Strong, early on, did the Court not rule or direct an importation of all of the information -- I'll call it information -- all of the discovery that was handed over and exchanged in the MDL handled by Judge Polster to this Court; and if so, was this thing, this piece of paper, this document, a part of that exchange?

MS. STRONG: My understanding, your Honor, is that he is referencing the West Virginia case, not the MDL. I don't believe we're in the case to which he is referring, but, again, I want to double-check that, but that's my understanding, your Honor.

So, no, I don't believe he's talking about materials that were produced in the MDL.

MR. PYSER: Your Honor, this is Steven Pyser, Cardinal Health. I am in the West Virginia case. That's why I raised it earlier as well. If I'm understanding Mr. Hanly correctly, what he's referring to,

that is not the case before Judge Polster. And as well, incorporating discovery into the record does not mean that an expert relied on it.

We have a report in this case in New York in which this document is not mentioned. If it was mentioned in another case in another opinion that takes different positions, I do not believe that the witness for the State can just incorporate every report that Dr. Lembke has ever written, including reports against Defendants -- excuse me -- including reports in cases in which some Defendants aren't even a part of. So we also object to the inclusion of this document.

THE COURT: I have a couple of points I'd suggest. You all entered into a Stipulation in connection with these hearings, part and parcel of that Stipulation was that any information, any documents that made their way into evidence in this case to which a party objects, that objection is preserved in the event of a trial.

The second point -- Mr. Hanly, this is directed to you. This Court made it -- and, by the way, it's directed to all counsel. This Court, in the last go-around, referenced a case, Guerra, G-U-E-R-R-A, versus D-I-T-T-A, 220 New York Slip Opinion 03771, a Second Department case that just came down in July of this year, and I believe -- I don't believe I know that the Court suggested, certainly the last session, perhaps the session before that, that in connection with these hearings, the Court was focusing in on two very specific areas, whether or not the methodology can meet the requirements of general acceptance, and whether or not if the methodology is appropriately applied, the results can be deemed reliable.

Of course, as noted in the Ditta case, that the actual question, the actual issue of whether or not the opinion will ever make its way to the finder of fact at trial relies upon the foundation that is laid by the person offering the evidence or the lack of foundation by the person or the entities or

the lawyers opposing it.

We're going a long way, we have been going a long way in both the direct examination and the cross-examination, and away from those two very, very basic precepts, general acceptance and reliability.

The doctor is, of course, permitted to -- all witnesses are permitted to, as a matter of fact, they're required to set forth their methodology, and the inference that the person offering the evidence seeks to gain from the Court, it's okay, it's generally accepted methodology, and whether or not the testimony indicates that the appropriate use of the methodology will result in a reliable conclusion, period.

That's the step one in what I call the "Fryebert" analysis. Step 2 will await, if need be, a trial. So here's my point -- by the way, Mr. Hanly, I ask this to everybody.

The Court, of course, has had an opportunity to review the decisions in the MDL concerning this witness, and it broke down to essentially two areas: a marketing

causation and a gateway argument or suggestion.

Are we beyond that in this case; meaning, is there something beyond those two general areas that you seek to elicit from this witness? I mean, I know I have nine points, but do the nine points fit within that framework that Judge Polster --

MR. HANLY: I think it's slightly broader at least than what your Honor just articulated, because Dr. Lembke's opinions include --

THE COURT: Gateway.

MR. HANLY: Gateway, supply, the effect of increased prescribing and so on. And, of course, the whole issue of marketing representations made by the Defendants.

Now, with respect to marketing causation as Judge Polster opined, that's something different from the ability of a witness, such as Dr. Lembke, to testify based upon her, her extensive work and her methodology, and her interaction with physicians throughout the United States that these marketing messages

have an influence.

That's a different, that's a different conclusion than the conclusion under some sort of marketing causation analysis.

THE COURT: He was clearly impressed with her credentials. I believe in the short version of his decision was as to marketing causation in the absence of some kind of marketing background, not only this witness, but another witness would be prohibited, although he does make it a point in his decision to say, in all other respects, that witness' opinions can be, can be pursued at trial.

MS. STRONG: Your Honor.

THE COURT: Yes. This is Ms. Strong?

MS. STRONG: Yes. This is Sabrina Strong on behalf of Johnson & Johnson.

I would just note that what Mr. Hanly said does not seem to comport with what Judge Polster decided. I'm reading from his opinion at page 12, and it says expressly (READING:) The Court finds Lembke may not testify regarding the effect that Defendants'

marketing and promotional efforts had on a doctor's prescribing practices.

He goes on to say he's excluding those opinions that purport to find Defendants' marketing efforts resulted in or caused increased sales and/or increased prescriptions of opioids.

I think that's precisely what Mr. Hanly was just referencing to you, your Honor, and that is an issue.

I would agree that the scope of his direct seems to be going far beyond what we're talking about in terms of marketing causation, which I think is what we're here for, your Honor, but I just wanted to make that point for clarity.

THE COURT: And as I noted at page 12, he also notes the Court's ruling does not in any way affect Lembke's remaining opinions, including the remainder of her 3rd and 5th opinions regarding the inaccuracy of statements and representations of Defendants' marketing materials and other promotional and/or educational efforts.

Here's my ruling. I'll sustain your objection.

And now we'll take a 15-minute break.

MS. STRONG: Thank you, your Honor.

(WHEREUPON, a short recess was taken.)

THE CLERK: Come to order. Part 48 is back in session.

THE COURT: Remind the witness, please.

THE CLERK: Oh, I'm sorry. I remind you, Doctor, you are still under oath.

MS. STRONG: Your Honor, it's Sabrina Strong. One note before we begin.

THE COURT: Wait a second. Say it again.

MS. STRONG: Just one note before we begin. Can we have a sense of how much longer Mr. Hanly intends to go?

This is one of those witnesses where we requested two days with her, but we were allotted one, and so we're concerned about the amount of time. He said he's at Opinion 3 of 9, I believe. Can we have some understanding in that regard?

THE COURT: Perhaps everyone will heed

the Court's instruction. I know Ms. Conroy did during her direct examination. So perhaps everybody will get on board the same way.

If I need more, I'll let you know. All right. I'd like to finish this witness today.

MR. HANLY: Judge, I'm happy to volunteer. I think maybe I have another hour tops.

THE COURT: Okay.

MS. STRONG: Okay. Good to know.

THE COURT: He said about another hour tops.

Do you know what "tops" means in lawyer language? Okay. Let's go from there. Go ahead.

MS. STRONG: Thank you, your Honor.

BY MR. HANLY:

Q. Doctor, I want to briefly go back to cover some aspects of the academic detailing that you discussed earlier, because it figures in the methodology and the bases for your opinion.

In the course of that academic

detailing, did you have available to you examples of marketing statements made by certain of the opioid manufacturers and other opioid-related companies?

A Yes.

Q. And did you study those statements in comparison to the medical literature that you reviewed?

A Yes.

Q. For example, if a marketing statement was to the effect that addiction is a rare occurrence, what corresponding scientific literature would you go to to see whether that statement was true or not?

A I would go to the literature looking at the risk of addiction in patients treated with prescription opioids.

Q. Does the body of medical literature that you relied upon, is there anything novel about these peer-reviewed papers such that they could not form a basis for -- a proper basis for an opinion that you would have concerning addiction?

A Well, many of the papers that purported to provide evidence on the risk of addiction were not actually founded in a methodology that could

reliably report that outcome.

Q. But my question, Doctor, is, is the use of scientific literature written by people other than you, is that a novel basis that an investigator, a researcher would have regard to?

A No, that's not novel.

Q. Is it -- is there any degree of reliability that is ascribed to that body of literature, assuming it's all or mostly peer-reviewed?

A Yes. So that's a foundational precept of academic scholarly work is to critically review the literature and that's --

Q. Now -- now, the marketing materials that you have reviewed in this case and that you reviewed prior to being involved in this case in preparing your, your book, did you try to determine when you were doing the academic detailing whether your own experience was similar to the experiences of other doctors who may or may not have received these sorts of marketing materials?

A Yes.

Q. And was there any consistency, or was there inconsistency?

A I heard a lot of inconsistency from my peers.

Q. Did that have any effect on your desire to continue the program of academic detailing?

A Yes. That motivated me to continue academic detailing.

Q. Did academic detailing to correct these misconceptions take up a small amount of time, a medium amount of time, a considerable amount of time, or what?

A A considerable amount of time, yes. In the last four to five years, I've spent a considerable amount of my professional time on this project.

Q. When you were academic detailing, did you receive from physicians, to whom you were providing this detailing, any anecdotes or recitations of experiences they had had in receiving and reviewing literature about the risks and benefits of opioids?

A Yes. I heard a large chorus of voices expressing a very similar experience and impression as my own.

Q. When you were taught in medical school,

were you taught anything about the addiction propensity of opioid medications?

A None.

Q. And what year, again, did you finish your medical school?

A 1995.

Q. Are you aware that on December the 12th 1995 the FDA approved the manufacture and sale of a drug called OxyContin?

A Yes.

Q. Now, I want to discuss briefly your -- the basis for your opinion and the methodology used to arrive thereat concerning whether a patient would need to have increased doses of an opioid over time and whether such increased doses would put the patient at risk of harm, okay?

A Okay.

Q. And among your opinions is, in sum and substance, that very opinion that increased doses put the patient at risk of harm; is that right?

A Yes.

Q. Did you just pull that opinion out of the air?

A No.

Q. Is that opinion shared by anybody else in the world, that you're aware of?

A Yes.

Q. Is that opinion, has the CDC, the Center For Disease Control, ever issued any data, or graphs, or anything else concerning whether increased dosages over time of opioids puts the patient at increased risk?

A Yes.

MR. HANLY: Okay. And could we have Slide Number 13, please.

BY MR. HANLY:

Q. Doctor, this slide is entitled Higher Dosage, Higher Risk, and it reads in part, and the footnote indicates that this is a publication made by the Centers for Disease Control and Prevention. Do you see that in Footnote Number 1?

A Yes.

Q. Okay. And we quoted a little bit from, from it (READING:) Higher dosages of opioids are associated with higher risk of overdose and death, even relatively low dosages, 20 to 15 morphine milligram equivalence, MME, per day, increased risk, higher doses haven't been shown to reduce pain over

the long term. Did I read that correctly?

A Yes.

Q. And what do we see? Explain to me and Justice Garguilo what we're seeing in these, in these two graphs.

A So the graph on the left with the purple line shows that as you go from low doses of prescription opioids to higher doses of prescription opioids, the risk of overdose death due to those opioids increases.

The graph on the right shows that as the yellow line shows, that as you go from lower doses of opioids to higher doses of opioids, the risk of any opioid overdose event increases, including nonlethal overdoses that often result in patients showing up in emergency rooms unconscious.

Q. So in both graphs what we're seeing, would it be fair to say, you take more of the stuff, you're increasing your risk of a bad outcome?

A Yes.

Q. And this Center for Disease Control piece of a report actually has two other footnotes referencing two other papers supportive of the statement in this document. Do you see that, three

and four?

A Yes. The Bonert paper, Number 3, the graph on the left comes from the Bonert paper, and the graph on the right comes from the Dunn paper.

Q. So my point is that this CDC publication is not the only document that you looked at or relied upon in reaching your opinion that increased dosage increases the risk of bad outcomes; is that fair?

A These are not the only documents I looked at. That is correct.

Q. And, in fact, so we have CDC, we have Bonert, we have Dunn, that's a total of three, but are there other papers peer-reviewed that are reliable that reach the same or similar conclusion that more drug that you give, the likelihood is you're going to have a bad event?

A Yes.

Q. And, by the way, Bonert is a publication, it looks like JAMA. Is that the Journal of the American Medical Association?

A Yes, it is.

Q. Is that a well-known journal?

A Yes.

Q. And the Dunn paper is from something called the Annals of Internal Medicine, right?

A Yes.

Q. Are those two publications, the Journal of the American Medical Association and the Annals of Internal Medicine, are they both peer-reviewed?

A Yes, they are.

Q. Are they regarded in the field of medicine as publications that will reliably publish material that those publications deem to be valid, truthful?

A In general, yes.

Q. Did you -- did any of these three publications, were any of these relied upon by you as a part of your methodology in coming to the higher dosage, higher risk opinion that you set forth?

A Yes.

Q. Now, have you -- we talked earlier about the marketing material that says that addiction is rare; do you remember that?

A Yes.

Q. And did you, in the course of your work in connection with this case, did you look at, try

to figure out what the real percentage risk of addiction is to patients administered opioid pain medications?

A Yes.

Q. And was your methodology any different in trying to come up with some statistics about the risk of addiction, was it any different from the methodology you described at the very beginning of this examination where you told Justice Garguilo about the importance of a thorough review of all parts of the pieces of medical literature? Did you do anything different in connection with --

A No.

Q. No? Is that what you said, Doctor?

A That's right. Sorry.

Q. Okay. And did you, in the course of your work, did you come across any papers that themselves tried to pull together the results of a number of other papers and set forth in that paper what the actual risk is of addiction related harms from opioids?

A Yes.

MR. HANLY: Okay. Can we put up Slide 14, please.

BY MR. HANLY:

Q. Now, Slide 14 is a chart that appears to have a source as two papers; do you see that?

A Yes, I do.

Q. So one paper is by someone named, Vowles, and the other by someone named Boscarino; is that correct?

A Yes.

Q. So please tell Justice Garguilo and us, what are we seeing in this graph, and what is the significance of this to your opinions, if any?

A So the study population being examined in both of these papers was specifically patients being prescribed opioids for chronic pain in order to determine the risk of addiction to opioids in that population.

And what we see here is that the Vowles article in 2015, which is in blue, found that approximately eight to 12 percent of chronic pain patients being prescribed opioids long-term will become severely addicted to opioids, and approximately 21 to 29 percent of those individuals will misuse opioids.

Boscarino was another study that

specifically looked at the risk of addiction in this population and found similar numbers based on the DSM-IV and the DSM-V criteria.

Q. Would any of these percentages 8 to 12, 13.2, 21 to 29, and 41.3, would any of those percentages, based upon your work over the decades in addiction medicine, be regarded as rare instances of adverse events?

A No. This would not be considered to be rare. This would be considered to be common.

Q. Now -- thank you. You can put that slide down, please.

Doctor, is there any amount of -- withdrawn.

In the course of your work in connection with this case, did you look at the question of whether limited use of opioid painkillers could result in an adverse event for the patient taking the medication?

A Yes.

Q. And did you look at any papers, peer-reviewed papers that relate to the question of limited use of the drug leading to a more persistent use and to an opioid use disorder?

A Yes.

MR. HANLY: Okay. Can we put up Slide Number 15, please. Judge, there's only 20 slides, so we're moving along pretty well.

THE COURT: Thank you.

BY MR. HANLY:

Q. And this slide is titled -- entitled: Even Limited Medical Exposure Can Lead To Persistent Use And OUD. That's opioid use disorder.

And tell the Judge what this is depicting.

A So these are data showing that patients who are prescribed opioids for surgery, for example in the Brummett paper, is thought to be an acute and self-limiting cause of pain, that 5.9 to 6.5 percent of those individuals will still be taking prescription opioids a year later.

So the important thing here is that they're not being diagnosed in this study with opioid use disorder addiction, but they're still taking the opioids a year later when one would have thought that their need for opioids would long be over.

That's relevant because we do know that

the longer that patients are taking opioids, the higher their risk of adverse health consequences, including, but not limited to, addiction.

The same thing with the Delgado paper showing that a very limited prescription for opioids for an ankle sprain, for example, to the, you know, relatively benign and self-limiting injury at 4.9 percent of individuals receiving an opioid for that type of injury will still be taking opioids a year later.

Schroeder actually looked at whether or not young people exposed to opioids through a dental procedure will develop opioid use disorder within one year and found that 6 percent of those individuals exposed to opioids for a wisdom tooth removal will be diagnosed with an opioid addiction within the year and 10 percent for women.

Q. Thank you, Doctor.

And this chart has three footnotes, and the footnotes are all to published papers, correct?

A That is correct.

Q. Okay. And the first one is a Journal of the American Medical Association, the surgery journal, correct?

A Yes.

Q. And the second, Delgado is a paper published in the Annals of Emergency Medicine?

A Yes.

Q. And the final footnote to Schroeder published in the Journal of the American Medical Association, Internal Medicine Journal, correct?

A Yes.

Q. All three of these journals of low regard, high regard, medium regard?

A These are all high regarded competitive journals.

Q. Are they all peer-reviewed?

A Yes.

Q. Did you rely upon the findings of these journals in connection with your work in this case?

A Yes.

Q. Is there any consensus in the medical literature relating to addiction medicine, including any reports of any organizations concerning the question of whether there's a relationship between increased supply of opioids in the country as a whole and adverse outcomes?

A Yes.

Q. And did you look at that issue in connection with your work in this case, the relationship between the supply and adverse outcomes for particular patients?

A Yes.

Q. And are there publications, peer-reviewed or otherwise, that address this issue?

A Yes.

MR. HANLY: Could we put up Slide Number 17, please.

BY MR. HANLY:

Q. And here what we've done with this slide is we've put two quotations from two separate reports side by side. On the left is a quotation from a report of the Association of Schools and Programs of Public Health, the ASPPH, correct?

A Yes.

Q. Please explain to Justice Garguilo what that association is.

A So it's an authoritative body on public health issues, including numerous very prominent public health universities, like Columbia, that came together to look at the opioid crisis to try to figure out what caused it and how to remedy it.

And they published a report bringing science to bear on opioids from which this quote was taken.

Q. And this quote, paraphrasing, is that the tremendous expansion of the supply led to scaled increases in prescription opioid dependence and to the transition of many to illicit opioids, including fentanyl, which have subsequently driven exponential increases in overdose, correct?

A Yes.

Q. And that quote came from a report of this organization published in 2019?

A Yes.

Q. On the right-hand side we have a quote from something called the National Academies of Sciences, Engineering and Medicine, sometimes called NASEM, correct?

A Yes.

Q. And just very briefly, what is that organization?

A Again, it's an authoritative body of experts who come together to weigh in on looking at the science regarding major issues related to science, engineering and medicine. In this case,

this was a paper they wrote on the opioid crisis.

Q. And that essentially -- paraphrasing it, it says the data presented make a prima facie case that heavy promotion of opioid prescribing by drug manufacturers, including misleading claims by some, and substantially increased prescribing by physicians were key contributors to the increase in misuse, OUD, and accompanying harms.

Did I read that correctly?

A Yes.

Q. And did you, with respect to these two publications, did you read the whole publication, or did you just look at the abstract?

A Yes, I read the whole publication.

Q. And did you, did you rely upon these publications, these specific publications concerning opioids in the course of carrying out your steps, your methods for reaching your opinions?

A Yes, but not exclusively.

Q. Okay. Well, tell Justice Garguilo again what the other reliance was.

A I relied on the CDC data showing that as opioid prescriptions increased, so did opioid-related overdose deaths and treatment

admissions.

I also relied on my clinical experience and my interviews with many of my colleagues in medicine. And in my clinical experience, I saw vastly increased opioid prescribing in the 1990s and more and more patients coming in with opioid addiction, more and more patients dying from opioid overdose.

Q. So, again, you analyzed the literature written by folks other than you, and you relied on what I've called your personal professional experience over more than two decades?

A Yes. That's right.

Q. In connection with your publications, we already discussed your research letter regarding prescribing to Medicare patients, correct?

A Yes.

Q. And there was another paper that you wrote and that was published concerning overprescribing; do you recall?

A Yes.

Q. And could you just tell Justice Garguilo what that second paper was about.

A We looked at which doctors in the United

States are prescribing opioids to try to detect whether or not there were geographic differences or differences by specialty.

And what we found was that by volume, primary care doctors prescribe the most opioids. That makes sense, because there are more of them than other types of doctors. And by specialty, it's pain medicine doctors that also -- that prescribe the most opioids.

But importantly what we saw was that there was not a small subset of so-called pill doctors driving the increased prescribing, that there was a wholesale paradigm shift and all doctors across all specialties were prescribing large amounts of opioids.

We also looked at geographic regions and found that there were no differences geographically. So all across the United States, there was an enormous uptick in opioid prescribing based on the data that we looked at. That was our findings.

THE COURT: Doctor, what constitutes overprescribing?

THE WITNESS: Well, overprescribing, certainly prescribing more than we were in

the 1990s, despite the fact that we have not seen an increased need for analgesia in this country.

Overprescribing we can also look at other countries, other developed nations and see how our prescribing compares to their prescribing and see that we are prescribing in some cases ten times more than other developed nations with aging populations and similar needs for analgesia.

So when I talk about overprescribing, I'm really comparing the way we prescribe now to the way that we prescribed before the Defendants launched their campaign in the 1990s promoting opioids.

THE COURT: Okay. Thank you.

BY MR. HANLY:

Q. Doctor, you, in the course of your answer that you just gave before Justice Garguilo's question, you talked about consistency of prescribing, prescribing habits across the nation, right?

A Yes.

Q. Now, did you look at any statistics on

the changes in the rate of prescribing in either New York State and/or Suffolk County and/or Nassau County?

A Yes.

Q. And can you just generally, without holding you to specific percentages, just describe generally for Justice Garguilo what you found and the extent to which, if any, that the trends, if any, that you saw are different from national trends?

A So we saw no difference in New York State compared to national trends. New York is in no way an outlier in terms of this phenomenon. And the same is true for Suffolk and Nassau County.

Q. Now, Doctor, Justice Garguilo mentioned, and you wrote in your book, and it's referred to elsewhere concerning a phenomenon or claimed phenomenon called the gateway effect, true?

A Yes.

Q. Just for clarity, would you just explain briefly what the gateway effect is?

A Patients who are prescribed opioids for a medical condition can go on to misuse the opioids that they have been personally prescribed, which

then subsequently can lead to a severe opioid addiction, including progression to the use of heroin and other illicit opioids.

Q. Is the gateway effect, does it have any acceptance, general acceptance or otherwise in the medical community to describe the phenomenon you just described?

A Yes. I would say it's strongly accepted in the medical community to describe what I just described.

Q. It's not a term that you just invented; is it?

A No.

Q. Is there support, is there reference in the medical literature to the gateway effect?

A Yes.

MR. HANLY: Could we put up Slide 18, please.

BY MR. HANLY:

Q. Now, Slide 18, am I correct, Doctor, this is -- we've pulled out some quotes from this National Academies report. It's called a consensus study report from NASEM, and it's entitled Pain Management and the Opioid Epidemic.

And the quote, first quote we have is: A preponderance of evidence suggests that the major increase in prescription opioid use beginning in the late 1990s has served as a gateway to increased heroin use.

And then below that, we pulled out the quote: In any related nature of the prescription in the illicit opioid epidemic means that one cannot be addressed separately from the other.

Did I read that correctly?

A Yes.

Q. And the second one, would that -- well, just state to the Court what the second sentence actually means in terms of prescription versus illegal drugs.

A It means that to really understand this opioid epidemic, we have to look at the way that we have been prescribing prescription opioids in the house of medicine.

That the problem of addiction and the problem of chronic pain and even nonchronic pain treated with opioids, those problems are deeply interrelated.

Q. And, Doctor, are there any studies that

you're aware of that have looked at the question of gateway effect in the State of New York?

A Yes.

MR. HANLY: Could we put up Slide Number 19, please.

BY MR. HANLY:

Q. Now, here we have some quotes from a paper by someone named Lankenau in the International Journal of Drug Policy; do you see that?

A Yes.

Q. And this study was actually a study of intravenous drug users in the City of New York and the City of Los Angeles; is that true?

A Yes.

Q. And we pulled out two quotes. One at the top, paraphrasing, initiation into opioid misuse was facilitated by easy access via participant's own prescription, family or friends, and occurred earlier than misuse of other drugs, of other illicit drugs. Prescription opioid misuse was a key feature of trajectories into injection drug use and/or heroin use.

Did I read that correctly?

A Yes.

Q. And then the second is the scientific literature has identified several specific subpopulations involved in prescription opioid misuse and diversion that are so diverse that it is not feasible to study them in a single investigation.

High school students, college students, older persons and women, most of whom initially obtain a prescription drug via legitimate medical practices, correct?

A Yes.

Q. Did you rely on this study for your opinion relating to the so-called gateway effect?

A Yes.

Q. Is this study, is this paper a peer-reviewed paper?

A Yes, it is.

Q. Is this a reliable, or highly regarded, or lowly regarded publication?

A This is a reliable source.

Q. What's happened between 2010 and 2017 with respect to New York State deaths from opioids?

A There has been an increase in opioid-related overdose deaths in the State of New

York in that timeframe.

MR. HANLY: Slide Number 20, the last slide, please.

BY MR. HANLY:

Q. Doctor, I guess it's pretty clear what this shows, but why don't you explain to Justice Garguilo and us.

A This shows that between 2010 and 2017 the number of opioid-related overdose deaths in persons aged 25 to 44 increased more than fourfold in the State of New York.

Q. And in a very -- in a slide very early in the examination, did we see an increase over roughly the same time period in the number of prescriptions written in New York State?

A Yes.

MR. HANLY: Thank you, Doctor. That's all I have.

THE WITNESS: Thank you.

THE COURT: Ms. Strong, it's almost 12:30. Do you want to get started, or would you prefer starting after the luncheon recess?

MS. STRONG: Let's just start after the

luncheon recess, your Honor.

THE COURT: Okay. We'll resume at 1:45.

MS. STRONG: Thank you, your Honor.

(WHEREUPON, after a luncheon recess, the following was had:)

MR. HANLY: Your Honor, before Ms. Strong begins, can I put something on the record?

THE COURT: Yes. First, remind the witness, then you can put something on the record.

THE CLERK: Doctor, I remind you you're still under oath.

THE WITNESS: Thank you.

MR. HANLY: Your Honor, I just wanted to place on the record, we had a dispute earlier in the examination concerning Slide Number 12. Representation was made by defense counsel, in effect, that we were ambushing them, they hadn't seen it.

I wish to point out to the Court and counsel that this slide, Exhibit 12, was a joint exhibit, Defendants' and Plaintiffs' Exhibit in the MDL, bearing number 17232, and

that exhibit, joint exhibit list was created and filed on September 25th 2019, which is a year ago.

THE COURT: Miss Strong, there was an indication that that piece of paper, that document, that thing, that exhibit was only used in West Virginia and not part and parcel of the MDL in Ohio, I just heard something otherwise.

MS. STRONG: I think the argument he's trying to make, your Honor, is that we knew of that underlying document period and the abstract. The question here is was that a document that Dr. Lembke relied upon in support of her opinions.

There are millions and millions of documents in this litigation, your Honor, and the question that we are here to address today is the basis for Dr. Lembke's opinions, and my point is that we -- the rules do not allow for us to be sandbagged by documents being presented to us the night before and saying she, too, is relying on these additional documents. That's the point, your

Honor.

THE COURT: Okay. So now we've heard ambushed and sandbag, all right.

MS. STRONG: I know you don't like those types of terms, but I think this is classic sandbagging, so I don't use those terms lightly, your Honor.

MR. SHKOLNIK: If I may, your Honor, Napoli Shkolnik, first of all, this is New York, and our rules do allow us to rely upon authoritative articles that come up that become available. There's no prejudice here. I think that's the rule in New York.

It is not sandbagging. I don't think it's appropriate to use here. They knew about this study, they knew about everything that we've listed for them, and it's inappropriate to suggest that it can't be utilized in this process before trial, which we could have supplemented even at that point. I just wanted to state based on New York practice.

THE COURT: If you were sitting here, what should I do?

MR. SHKOLNIK: You've already done it, your Honor. It's in the record. You'll consider it, use it for what it's worth, and it's really a nonissue.

THE COURT: Here's a fair compromise. If accepted, it will go to weight, to the weight of the evidence, and not to the -- whatever the opposite of the weight is.

MR. SHKOLNIK: And I'm sorry for talking through the mask, I apologize.

THE COURT: Doctor, are you ready?

THE WITNESS: Yes.

THE COURT: Miss Strong, go ahead.

MS. STRONG: And, Mr. Pyser, did you want to say something before I begin? I just didn't want to interrupt. Because I see you on my screen.

MR. PYSER: No, that's okay.

MS. STRONG: Okay. Thank you.

THE COURT: Did I step on your order?

MS. STRONG: No. No, no, no. You're doing it correctly. It's just Mr. Pyser is up on my screen, and I know he's examining today, I didn't know if he wanted to say

anything more before we begin, your Honor.

THE COURT: He's very big on my screen, too.

MR. PYSER: And I apologize to all of you.

EXAMINATION BY

MS. STRONG:

Q. Good afternoon, Dr. Lembke.

A Good afternoon.

Q. My name is Sabrina Strong, and I represent Johnson & Johnson and Janssen in this litigation. I want to turn first to some specifics about your training and experience.

You're not an economist, correct?

A That is correct.

Q. You do not have a degree or training in marketing, correct?

A That is correct.

Q. You do not have any employment experience working in the field of pharmaceutical marketing; do you?

A No.

Q. You don't belong to any professional associations in the field of pharmaceutical

marketing either, correct?

A That's correct.

Q. You also do not have any experience regarding FDA regulations that govern pharmaceutical marketing, correct?

A That's correct.

Q. You do not have any degrees or training in pharmacoeconomics?

A Since I don't know what that is, the answer is no.

Q. We'll skip that.

You're aware that there is a scientific field called econometrics, correct?

A Yes.

Q. Are you aware that that field applies statistical methods to economic data?

A Yes.

Q. But you do not have any degrees or training in econometrics of sales or marketing, correct?

A That is correct.

Q. Okay. So you're testifying here today as a retained expert for the Plaintiffs, which in this case it's the State of New York, Nassau County,

Suffolk County, correct?

A Yes.

Q. But before this case, you were retained by the Plaintiffs in the federal multidistrict litigation pending in Cleveland, Ohio, correct?

A Yes.

Q. You submitted a report in connection with that MDL proceeding, right?

A Yes.

(Video disconnected.)

THE COURT: We're back, doctor, to a degree.

MS. STRONG: It sounds like everybody got kicked off, your Honor; is that right?

THE COURT: Yes. We're almost back on. They're just testing.

MS. STRONG: Ready, your Honor.

THE COURT: Back on board. Let's go.

MS. STRONG: Okay.

Q. So I was just asking you, Dr. Lembke, about the report you submitted in the MDL, and you confirmed that you did submit a report in the MDL proceeding, correct?

A Yes.

Q. Okay. And there are some structural differences between your report in the MDL and your report here, but the opinions in both are the same, correct?

A Yes.

Q. You understand that Judge Polster, in the federal MDL proceeding, ruled that he would not be permitted to opine on marketing causation in his court, because you do not have the marketing expertise necessary to offer those causation opinions, correct?

A Yes.

Q. Okay. And you have distinguished the question of whether opioid marketing material was consistent or inconsistent with scientific evidence from the question of causation, correct?

A Yes.

MS. STRONG: Okay. And so we put together a demonstrative that draws out that distinction.

And, Pam, if you're able to, can you pull up Slide 1, and I believe it's being handed out in the court at this time as well, or I would ask Mr. Asher to do so.

Q. And so I'd like you to look at these questions, Dr. Lembke.

Question 1 is: Was each Defendant's promotion, if any, informed by scientific evidence?

Question 2: If not, did misleading promotion by any Defendant cause doctors to write medically inappropriate prescriptions?

And then there's a third question, apart from that distinction that you made between 1 and 2, the third question is: Did those prescriptions, if any, lead to opioid addiction, misuse or overdose?

Do you see those questions, Dr. Lembke?

A Yes, I do.

Q. You spent a considerable amount of time with Mr. Hanly talking about question 1, but I want to focus on questions 2 and 3.

And so with that, Pam, if you can pull that down, and I'll ask you some questions focusing on that second question.

So let's talk about a doctor's decision to prescribe medications to a patient.

At a high level you agree that opioid prescribing practices depends largely on the doctor, correct?

A No.

Q. Well, you would agree that there is a huge variation in opioid prescribing across the country and it continues to depend largely on the doctor, right?

A No.

Q. Okay. Do you recall being deposed in this case, Dr. Lembke, on January 16th 2020?

A Yes.

Q. Okay. And I would like to show you a portion of your deposition testimony. For your benefit and for the Court's benefit, I'd like to refer you to page 54.

If Pam can put this up on the screen, page 54, lines 15 through lines 24.

THE COURT: Okay.

MS. STRONG: And I don't know if you have your transcripts with you, Dr. Lembke, or if you prefer to read it off the screen.

Q. Can you read that okay, Dr. Lembke?

A Yes.

Q. Okay. And at your deposition on January 16th 2020 here in the New York case, you were asked the following question:

"Has the number of pills in a prescription for three weeks of opioids remained the same over the past decade?

ANSWER: There is huge variation in opioid prescribing across the country. In some geographic regions opioid prescribing has decreased rapidly. In others, it has not. It really depends on which doctor.

QUESTION: So it depends on the doctors then?

ANSWER: It continues to depend largely on the doctor, yes."

Is that the testimony that you gave at your deposition in this case, Dr. Lembke?

A Yes, it is.

Q. Okay. And doctors are expected to weigh the risks and benefits of any prescription medication for each particular patient before deciding to prescribe it, correct?

A Yes.

Q. For example, there are numerous patient-specific risk factors for opioid addiction, right, you believe that?

A I'm sorry, can you repeat the question.

Q. I can.

There are numerous patient-specific risk factors for opioid addiction, correct?

A Yes.

Q. One of those risk factors is personal history of substance abuse?

A Yes.

Q. Another is family history of substance abuse?

A Yes.

Q. Childhood trauma is another factor?

A Yes.

Q. And psychiatric comorbidity, correct?

A Yes.

Q. And by that, just for the benefit of the Court and for clarity, you mean an individual who has a psychiatric disorder, other than the disease of addiction, which could include everything from major depression, obsessive compulsive disorder, bipolar disorder and schizophrenia, correct?

A Yes.

Q. Although you've traveled to New York and you've talked with some doctors in New York, you do not know whether you have talked with any doctor who

practices in Nassau County about his or her experiences with prescription opioids, correct?

A That is correct.

Q. And the same is true for Suffolk County, you do not know whether you have ever talked with a doctor who practices in Suffolk County about his or her experience with prescription opioids, correct?

A Yes.

Q. In fact, the only doctors in New York who prescribe opioids that you can identify are doctors reported in lay-newspapers as operating pill mills, correct?

A I'm sorry, could you say that again.

Q. Absolutely.

The only doctors in New York who prescribed opioids who you could identify are doctors reported in lay-newspapers as operating pill mills, correct?

A No, that's not correct.

Q. And, again, I'd like to pull up -- I would like you to look at a portion of your deposition testimony in this case, the January 16th 2020 deposition. For everyone's benefit we're turning to page 207, lines 4 through 10.

Pam, if you could put that up and everyone can take a moment to get their place, page 207.

You were asked at your deposition, question, line 4.

"So these are reports in the newspaper about pill mill doctors in New York?

ANSWER: That's right.

QUESTION: Okay. Other than that, can you give -- identify any doctor who prescribed opioid medications to any individuals in New York?

ANSWER: No."

Dr. Lembke, that was the testimony that you gave at your deposition in January, correct?

A Yes.

Q. So that means you didn't try to identify which doctors in New York, if any, saw any of the specific marketing materials you identified as problematic in your report, correct?

A No, that's incorrect.

Q. Well, you didn't identify any doctors who relied upon any specific marketing materials, correct, in describing decisions?

A That is incorrect.

Q. Okay. Did you identify in your report any doctors or the scope of doctors who you believed saw a particular Defendant marketing materials and actually relied upon it in making a decision; did you identify those folks in your report?

A Not in my report, no.

Q. Did you identify them at your deposition?

A No.

Q. In forming your opinions, in forming your opinions you also didn't conduct a survey of New York doctors to try to understand what factors they considered in deciding to prescribe opioid medication to any particular patient; did you?

A What do you mean by "a survey?"

Q. Well, I'm not talking about anecdotes. I'm talking about a scientifically rigorous survey.

You didn't conduct a survey to understand what factors any New York doctor considered in deciding to prescribe an opioid medication to any particular patient, correct?

A No.

Q. And you also did not conduct a survey of New York doctors to try to learn what marketing

materials, if any, the prescribers in New York may have received from each individual Defendant, that was not part of your methodology in coming up with your opinions in this case, correct?

A No, that's incorrect.

Q. You conducted a survey, a scientifically rigorous survey to try to learn what marketing materials, if any, a prescriber in New York saw, may have received from each Defendant?

A So in the research for my book I conducted quantitative interviews with doctors providing what they relied upon in their opioid prescribing, including some healthcare professionals in New York.

Q. Okay. So I, I would like you to turn to your January 16th 2020 deposition. If we can pull that up again. It's page 175, line 5, and it runs to line 20. Pam, you've got that on the screen.

Dr. Lembke, you were asked at your deposition:

"So you conducted no comprehensive survey of doctors and nurses in New York to understand what marketing materials, if any, prescribers in New York received from what

individual Defendants; is that correct?"

A It's correct that the survey --

Q. Let me finish the question.

A I'm sorry.

Q. And so the transcript goes on to say: "I feel like I answered the question to the best of my ability."

A follow-up question is asked at line 12: "So do you have a survey that you can show us where you surveyed doctors and nurses in New York regarding asking them, for example, Mallinckrodt, what specific marketing materials did you, Dr. Smith, in Nassau, receive from Mallinckrodt; do you have that to produce?

ANSWER: I don't have a survey at that level of specificity."

That's your testimony from your deposition, correct, Dr. Lembke?

A Yes.

Q. Okay. And you did not do a regression analysis as part of your methodology; did you?

A No.

Q. So to be clear to the Court, make sure we're on the same page, was there a regression

analysis, is a tool that's employed to try to isolate the impact of one factor on another while controlling for potentially confounding factors, correct?

A Yes.

Q. Okay. And we've been talking about doctors -- I want to shift gears for a moment.

Pam, can you actually put up Slide 1 for us again one more time.

I want to remind you of what question 3 is. It says: "Did those prescriptions, if any, lead to opioid addiction and misuse of use or overdose?"

All right. So, Pam, you can pull that back down.

And so with that in mind, turning to patients, in forming your opinions, you haven't examined patient outcomes for any particular patient in the State of New York who was prescribed one of the Defendants' opioid medications; have you?

A In my book I describe a patient who I interviewed using qualitative methods who was prescribed an opioid in the State of New York.

Q. So in forming your opinions you relied

upon that, that's your experience from New York, that one anecdote?

A That is part of my experience for New York, yes.

Q. Okay. So you've not done anything more to examine patient outcomes for any particular patient in the State of New York who was prescribed one of the Defendants' opioid medications; have you?

A Not by directly interviewing a patient, no.

Q. And you didn't review individual medical records either, correct?

A Correct.

Q. And you didn't actually speak to any patients in Nassau or Suffolk County for purposes of forming your opinions in this case at all, correct?

A Correct.

Q. And you mentioned that one anecdote in your book. Which drug did the patient take?

A She was prescribed buprenorphine.

Q. Any other drug?

A No.

Q. So given that you didn't examine patients broadly in forming your opinions, other

than the one anecdote you gave us, you didn't talk to folks in Nassau or Suffolk, you didn't talk to patients there, that means that you didn't consider, as part of your methodology, whether any particular patient in New York suffering from chronic pain actually benefited from Defendants' opioid medications, correct?

A I'm sorry, could you restate the question?

Q. Sure.

Given what you've said, as part of your methodology you didn't consider whether any particular patient in New York who suffers from chronic pain actually benefited from Defendants' opioid medications, correct?

A I did have conversations with patients in New York, others beyond the one that was in my book regarding whether or not they benefited from opioid medications.

Q. So you got some anecdotal conversations, that's what you're referring to?

A I have conversations that I think go beyond anecdote.

Q. Okay. But you just testified in forming

your opinions in this case you didn't review individual medical records or talk with patients in coming up with your opinions in this case; isn't that correct?

A I didn't review medical records, but I did talk to patients.

Q. Anecdotally?

A I think they were interviews based on quantitative methodology.

Q. And are they identified in your expert report, Dr. Lembke, in things that you relied upon in forming your opinions in this case?

A No. We did not identify individual patients in my report.

Q. Because that's not part of your methodology in forming your opinions in this case, correct, Dr. Lembke?

A No, that's not correct.

Q. So you have a methodology that you failed to disclose to us, Dr. Lembke; is that your testimony?

A No.

Q. Okay. You haven't looked at individual prescribing decisions of doctors in New York, and

you haven't surveyed them for purposes of in terms of a scientifically rigorous survey for coming up with your, your opinions here, but your analysis does depend, in part, on your belief that there's no reliable evidence that long-term opioid therapy is effective for chronic non-cancer pain, correct?

A Yes.

Q. You recognize that the FDA has approved certain prescription opioid medications for the management of chronic pain, right?

A Yes.

Q. And, for example, the FDA has approved Nucynta Er with the indication for management of chronic pain, correct?

A Yes.

Q. The same is true for Duragesic?

A Yes.

Q. The same is true for Exalgo?

A Yes.

Q. The same is true for Kadian, correct?

A Yes.

Q. There are a number of generic drugs, generic long-acting opioids that are also approved for the management of chronic pain, correct?

A Yes.

Q. Some of those medications are manufactured by some of the Defendants in this case, correct?

A Yes.

Q. You understand that before approving any prescription opioid medication the FDA must determine that it's safe and effective?

A Well, I just lost sound. Can you repeat that?

Q. Yes.

Can you hear me okay?

A Yeah.

Q. We have some volume, some noise. I don't know if you can hear it.

A I hear some static, which makes it harder to hear you.

Q. Yes. I think it's gone now, Dr. Lembke. Can you hear me better?

A Yes. Thank you.

Q. So my question was: You understand that before approving any prescription opioid medication the FDA must determine that it's safe and effective for its indicated use, correct?

A Yes, I understand that.

Q. You also understand that for a drug to be approved for marketing FDA must determine that the drug is effective and that the benefits outweigh its potential risk to patients; is that right?

A Yes.

Q. But you don't believe that the totality of the evidence that the FDA reviewed in connection with approving prescription opioid medications for treatment of chronic pain support that indication, correct?

A That is correct.

Q. In your opinion, Dr. Lembke, the FDA was just wrong on this issue, correct?

A They were wrong and also to some extent duped.

Q. Do you believe they were wrong, Dr. Lembke? That's my question. I would like you to answer my questions.

A Yes.

Q. So putting aside some of the details that we just covered, at bottom you believe that doctors have prescribed too many opioid medications, correct?

A Yes.

Q. As part of your work in this case, you've not identified any specific prescription for an opioid medication written in the State of New York that you believe is medically unnecessary, correct?

And, again, I'm focused on your work in forming your opinions for this case, that which was disclosed to the Defendants. I'm not talking about anecdotal conversations you may or may not have had. I'm really trying to focus on the basis of your opinions in this case as disclosed to the parties.

So do you need me to repeat the question?

A Sure.

Q. So as part of your work in this case, in forming your opinions here you have not identified any specific prescription for an opioid medication written in the State of New York that you believe is medically unnecessary, correct?

A It's hard for me to answer that yes or no. I did research for my book, which preceded my involvement in this litigation, which just formed my opinion, and in that process I did qualitative

interviews, including with individuals in New York State.

Q. Okay. Just so we have absolute clarity on this, why don't we go ahead and turn to page 207 of your January 2020 deposition. For everyone in the courtroom it's page 207, lines 21, and it runs on to page 208, line 3. Pam has pulled it up. Thank you very much, Pam.

So at line 21 you were asked:

"So my question was a bit different, so let me just ask this: Is your opinion in this case based on identifying concrete examples of specific prescriptions of any opioids written in New York that you believe, in your opinion, were medically unnecessary or inappropriate?

ANSWER: My opinion is not based on specific prescriptions, it's based on aggregate prescriptions."

That was the testimony that you gave in your deposition in this case, correct?

A Yes.

Q. Did you include those qualitative interviews that you just referenced? Did you include those interviews in your expert materials in

this case?

A Yes.

Q. Okay. And can you identify where those are located in your expert materials?

A Defense asked for those documents. They were copied and given to defense counsel. They were used in deposition. I was asked questions regarding those documents in deposition.

Q. And you gave the answer, the aggregate prescription is what you relied upon. That's what you testified to at the deposition, right?

Your opinion is not based on specific prescriptions, in terms of forming your opinion in this case, it was based on aggregate prescriptions, correct?

A That is what I testified at the deposition, yes.

Q. And you can't point to any particular prescription for any Janssen opioid medications and tell the jury that those are medically unnecessary, that's not something that you're going to do in this case, correct?

A No.

THE COURT: "No," or "no," not correct?

THE WITNESS: Sorry. Ask the question again.

Q. So I'll rephrase it a little bit.

You can't point to any particular prescription for any Janssen opioid medications and tell the jury that those are medically unnecessary?

A No, I cannot point to any specific Janssen prescriptions.

Q. The same is true for Allergan, correct?

A Yes.

Q. And Teva?

A Yes.

Q. Endo?

A Yes.

Q. Mallinckrodt?

A Yes.

Q. So your opinion in this case instead is that the total number of opioid prescriptions written was too many, right?

A Yes.

Q. Even though you're focused on the total number of opioid prescriptions, you still don't know what the right number of opioid prescriptions is, correct?

A I don't think that's correct. No, I do have an opinion about that.

Q. Okay. So let's go and pull up your deposition. It's page 115 -- let me ask it slightly differently before we do that, Pam, actually, one moment.

You don't know the right number of patients -- I mean, let's set aside total number of prescriptions. You don't know the right number of patients who should be prescribed opioid medications in this country are in New York or not; do you?

A Well, I'm not sure what you mean by "the right number." I mean, I don't have a specific number. I do have an opinion that we should be prescribing a lot less than we're currently prescribing and for a much narrower indication.

Q. Okay. So you think it should be less, but my question is what is the right number? You don't know what the right number of prescriptions is, correct?

A I have not calculated a single number, no.

Q. And, in fact, the most you've testified to at your deposition is you said: It's hard to say

what the number should be. I think it should be lower. Correct? That's what you said at your deposition?

A Yes.

Q. Okay. So that means you can't tell the Court, for example, how many fewer Kadian prescriptions should have been written, correct?

A As I said to the Judge earlier, a rough estimate is that we're writing four to five times too many opioid prescriptions compared to what we were writing in the 1990s. So that could also apply to Kadian's products.

Q. Is it your opinion that the correct number of prescriptions is those that were written in 1990?

A I think we were closer to what was appropriate for the actual need for analgesia in the population.

Q. And that was -- in 1990 you do understand that the Defendants' products mostly did not exist, correct? Do you understand that?

A There are a lot of products. I don't know the exact dates of every single product and when it came out on the market.

Q. So you don't know that most of the Defendants' products at issue in this case didn't exist in 1990; is that your testimony, Dr. Lembke?

A I'd like to see the material on that. I'm happy to review any additional material.

Q. I'm just asking if you happen to know as an expert opining in this case, whether the vast majority of the products at issue in this case did not exist in 1990; do you know that or not?

A Well, I, I would disagree that it's the vast majority. Morphine was available, OxyContin was available, hydrocodone products were available.

Q. I'm talking about the Defendants' branded products at issue in this litigation as a starting point, most of them did not exist; do you know that or not?

If you don't, that's fine, Dr. Lembke. I'm just trying to get an understanding of your knowledge of those medications.

A Well, you're wanting me to agree with the statement that I'm reluctant to agree with, because I would want to see more material.

Q. Because you don't know, without seeing more material, you can't tell me; is that fair to

say?

A Yes, that is fair to say.

Q. Okay. And, you know, I just want to ask a couple more on this point, because I think it's important for us all to be clear on this.

Right now sitting here today, you can't testify as to how many fewer Nucynta prescriptions should have been written at any point in time, correct?

And, I mean, you know, how many should have been written or should not have been written, you can't do that as you sit here today, correct?

A I can't provide a specific number, no.

Q. The same is true for Exalgo?

A Yes.

Q. Actiq?

A Yes.

Q. That's really true for any individual opioid medications that were sold or distributed or dispensed by any Defendants in this case, correct?

A Yes.

Q. So let's talk more about the factors that led to the number of prescriptions of opioids in New York, generally in Suffolk and Nassau County

specifically.

You do agree that some doctors actually prescribed opioids purely for their own personal profit knowing that the individuals to whom they were prescribing didn't really need the medications, correct?

A Yes.

Q. Doctors who prescribe opioids to people knowing that they don't actually need the medications, those doctors are commonly referred to as pill mill doctors, correct?

A Yes.

Q. They're not prescribing opioids because they believe the prescriptions are appropriate based on anything anyone said, correct?

A Yes.

Q. That would include Defendants, they're not doing it based on anything the Defendants said when they're out there committing those crimes, correct?

A Yes.

Q. You do recognize that pill mills have contributed to the opioid problem, correct?

A Yes.

Q. You're aware, from at least lay-newspaper articles, I believe you identified those before, that there have been pill mill doctors in New York, right?

A Yes.

Q. But you can't identify any specific pill mills in New York State, correct?

A Correct.

Q. So it's fair to say that you haven't taken steps to measure or quantify the impact of pill mills in causing opioid abuse, misuse or overdose, that wasn't part of your methodology, correct?

A That's incorrect.

Q. Okay. So let me go here.

I understand you published an article in JAMA in 2016 with Jonathan Chen, an altered view of 2013 Medicaid data on opioid prescribing; are you pausing because of that?

A Yes.

Q. Okay. So you know that -- and thanks for that Medicare data -- you know that many pill mill doctors actually run all cash businesses and don't accept insurance, correct?

A Yes.

Q. And Medicare is a form of insurance, right?

A Yes, it is. Yes.

Q. I need an oral answer for the transcript. Thanks, Dr. Lembke.

If pill mill doctors don't accept an insurance, their prescriptions wouldn't show up in Medicare data, correct?

A That's true.

Q. So setting aside that in your 2006 JAMA article addressing Medicare data you conclude -- I'm sorry, setting that aside, in that article you conclude that the overall increase in opioid prescribing was not primarily due to pill mill doctors, correct?

A That's correct.

Q. Okay. But the article doesn't address the impact of pill mill prescribers on specific patient outcomes, correct?

A That is true.

Q. Okay. And so nothing in the article directly quantifies the impact of prescriptions from pill mill doctors on opioid abuse, misuse and

overdose, fair?

A That is fair.

Q. So let's talk about doctor shopping next.

You agree that in some circumstances patients themselves engage in manipulative behaviors to obtain opioid medications from doctors, right?

A Yes.

Q. And one example is you know of a patient manipulating a prescriber is when a patient goes to multiple doctors to get the same or similar prescriptions, right?

A Yes.

Q. That's called doctor shopping; isn't it?

A Yes, that's correct.

Q. To be clear, doctor shopping patients essentially lie to their doctors to get more opioid prescriptions, correct?

A Yes.

Q. You would agree that doctor shopping often leads to improper prescriptions, right?

A Yes.

Q. You would agree that doctor shopping is certainly part of the opioid abuse problem in New

York, correct?

A Yes.

Q. Well, one way to identify patients who may be doctor shopping is to look at the data maintained by a state's prescription drug monitoring program, correct?

A Yes.

Q. You haven't looked at New York's prescription drug monitoring program data in forming your opinions in this case, correct?

A That's correct.

Q. So that means you have not tried to identify how many prescription opioid pills were dispensed improperly as a result of doctor shopping, fair?

A Not by looking at the prescription drug monitoring database.

Q. Well, it wasn't part of your methodology in this case to actually measure the impact of doctor shopping on the opioid abuse problem in New York, correct?

A That is correct.

Q. So let's turn to opioid prescriptions that were illegally obtained without any

prescription at all.

Illegally obtaining opioid medications is often referred to as diversion, correct?

A Yes.

Q. Do you agree that sometimes prescription opioid pills are stolen from production facilities during transit from production facilities or from retail pharmacies; is that right?

A Yes.

Q. Opioid pills that were diverted from production facilities, pharmacies or during transit were not prescribed by a doctor, correct?

A That is correct.

Q. You agree that this type of diversion has been part of the opioid abuse problem in New York, right?

A Yes.

Q. But you've not identified the number of these incidents of diversion in forming your causation opinion in this case; have you?

A No.

Q. You don't know what percentage of pills are diverted from pharmacies or distributors; do you?

A No.

Q. In fact, you aren't even offering an opinion on thefts from pharmacies or distributors in this case, correct?

A Pardon me?

Q. I just want to make sure you weren't offering an opinion on thefts from pharmacies or distributors in this case, correct? Right?

A I can't answer that yes or no.

Q. Well, let me try, I'm going to rephrase it one more time and see if we can do this before we go to the deposition.

Are you offering any opinion in this case about any theft from a distributor in this case?

A I am offering opinion on diversion but not specifically necessarily due to theft.

Q. Okay. So I just really need you to focus on the question. That was my question.

You're not offering opinions on thefts from pharmacies or distributors in this case, correct?

A Correct.

Q. And so it's fair to say that you've not

tried to quantify the impact of this type of diversion on the opioid abuse crisis in New York; it's not part of your methodology to quantify this diversion, correct?

A That's correct.

Q. One of your opinions in this case is that increased supply of prescription opioids contributed to more individuals turning to heroin, correct?

A Yes.

Q. You agree that heroin and other illicitly manufactured opioids are supplied by drug dealers and cartels, right?

A Yes.

Q. Despite opining on what you believe was the cause of heroin use, are you aware that there were many -- there were more heroin users in New York City in the mid 1970s than in 2000?

A I haven't seen material to that effect, but I'm happy to review, and if you have something you want me to read.

Q. So you're not aware of that; is that your testimony?

A Yes.

Q. You're not aware of it, correct?

A That's correct.

Q. No part of your methodology involved looking at the illicitly manufactured opioid market in New York, correct?

A That's correct.

Q. So let's talk more about the things that may have harmed New York residents.

For example, do you believe that other pharmaceutical companies, that are not Defendants in this case, contributed to opioid related harms in New York, right?

A I'm sorry, could you --

Q. Do you want me to say it again?

A There are a lot of Defendants in this case. Are you referring to a specific opioid manufacturing --

Q. Right now as you sit here, do you believe that other pharmaceutical companies, other than the Defendants in this case, contributed to opioid related harms in New York?

A Yes. I mean, I, I look at it as a sort of aggregate influence.

Q. Okay. And do you believe that doctors

contributed to opioid related harms in New York, correct?

A Yes.

Q. The FDA also contributed to the harms in your opinion, correct?

A Yes.

Q. State Medical Boards and the Federation of State Medical Boards also contributed?

A Yes.

Q. Formulary and reimbursement policies of insurance companies and other third-party pairs also contributed in your opinion, correct?

A Yes.

Q. So let's talk a little bit about each of those.

Although you believe that there are pharmaceutical companies other than the Defendants here that bear some responsibility, you have not, as part of your opinion in this case, quantified the contribution of those non-Defendant pharmaceutical companies; have you?

A No.

Q. When you say doctors bear some responsibility, that means all doctors, not just the

pill mill doctors we discussed before, correct?

A Yes.

Q. Then in the course of writing your book you took notes reflecting that some of your colleagues just want to keep the emergency room moving by getting patients out the door, right?

A Yes.

Q. One of your trusted colleagues said, Just give them what they want, right?

A Yes, she did.

Q. But you haven't quantified the extent to which doctors have contributed to the opioid crisis in New York, correct?

A Not to a specific number, no.

Q. And as we discussed earlier, you think the FDA got it wrong when they approved opioid medications for the treatment of chronic pain, correct? I just want to make sure we're back on the same page there.

A Yes.

Q. You also believe that the FDA contributed to the prescription opioid epidemic by making it easier, because I'm quoting from you, making it easier for the pharmaceutical companies to

get FDA approval from new opioids coming on the market; is that fair?

A Yes.

Q. But there's no portion of your methodology where you quantify the degree of responsibility that should be allocated to FDA, correct?

A That's correct.

Q. So let's talk about some of the other regulatory authorities.

The New York Board of Medicine has the power to investigate and discipline doctors, correct?

A Yes.

Q. It also imposes and overseas continuing medical education, or CME requirements; doesn't it?

A Yes.

Q. The New York Board of Medicine has the authority to revoke medical licenses, correct?

A Yes, it does.

Q. If a doctor has his or her license revoked, the doctor can't prescribe opioid medications, correct?

A Not lawfully.

Q. So that's correct?

A That's correct.

Q. And you agree that State Medical Boards, including the New York Board of Medicine, contributed to the opioid-related harms, right?

A Yes.

Q. But there's no part of your methodology that quantifies the degree of responsibility that should be allocated to the New York Board of Medicine, correct?

A That's correct.

Q. You also think that model opioid prescribing guidelines released by the Federation of State Medical Boards made the opioid epidemic in New York worse, right?

A Yes.

Q. So we've talked about a few government regulatory agencies now but, again, to be clear, no part of your methodology quantifies the responsibility of any government or regulatory entity, fair?

A Yes.

Q. You also don't, as part of your -- as part of your methodology in this case, you don't

quantify the extent to which managed care formulary or other reimbursement policies caused or contributed to the opioid epidemic in New York, correct?

A That's correct.

Q. But you agree that managed care formulary, other reimbursement policies did influence how medication is prescribed, right?

A Yes.

Q. So we've talked about a number of individuals and entities and other factors that you believe contributed to the opioid crisis.

I'd ask Pam now to pull up Slide 2 and, Mr. Asher, if you can, hand that out in court. This one will be pretty quick. And if you can go ahead and pull that up.

So, again, we've talked about a number of individuals and entities and other factors that you believed contributed to the opioid crisis, and I think they'll pop up on the screen here in a moment.

But to be clear, Dr. Lembke, you've not specifically quantified the responsibility of any of those factors; have you?

A Not with a specific number, no.

MS. STRONG: Okay. So we just don't know.

No further questions at this time, your Honor. Thank you, Dr. Lembke.

THE WITNESS: You're welcome.

MR. PYSER: Your Honor, this is Steven Pyser, I'm up next. Completely up to the Court if you want to take a break now or you just want me to jump in.

THE COURT: We're only working for an hour, so jump in.

THE WITNESS: Mr. Pyser, can you improve your sound at all? The sound is not good on my end, neither is my hearing.

MR. PYSER: I will do my best to improve my sound.

CROSS-EXAMINATION

MR. PYSER:

Q. Dr. Lembke, I just want to start with some questions about your personal experience.

Have you ever worked for a pharmaceutical wholesale distributor?

A No.

Q. Do you have any training or expertise in

supply chain management?

A No.

Q. Do you have any training or expertise in the distribution of controlled substances?

A No.

Q. Do you have any training or expertise in suspicious order monitoring for controlled substances?

A No.

Q. Do you have any training or expertise in a distributor's legal or regulatory responsibilities concerning distribution of controlled substances?

A I am aware of the Controlled Substances Act and its statement that every player in the supply chain has a responsibility to steward those pills and to monitor suspicious orders.

Q. But you don't have any expertise in a distributor's legal or regulatory responsibilities with respect to controlled substances; do you?

A I don't have specific training beyond my medical training and my medical experience, no.

Q. Doctor, if you could, Dr. Lembke, do you recall giving a deposition in the MDL case on April 24th 2019?

A Yes, I recall giving that deposition.

Q. Now, if you're able to control the screen and bring up page 276, lines 5 through 9, and in that deposition you were asked:

"Do you have any training or expertise in a distributor's legal or regulatory responsibilities concerning the distribution of controlled substances?"

And you answered: "No."

Is that the testimony you gave under oath?

A Yes.

Q. Have you ever designed a suspicious order monitoring program?

A Yes.

Q. Dr. Lembke, you recall being deposed in this case in New York?

A Yes.

MR. PYSER: Matt, if you can pull up the January 16th 2020 deposition transcript at page 170, line 24, through 171, line 1.

Q. You were asked:

"Have you ever designed a suspicious order monitoring program?"

And you answered: "No."

Was that the testimony you gave under oath?

A Yes.

Q. Dr. Lembke, I'd like to ask you a little bit about something from your report on page 13 of your report in paragraph 2. If you have it handy I can read it to you as well. You wrote the following: "Opioid prescribing began to increase in the 1980s and became prolific in the 1990s and the early part of the 21st century representing a radical part on shift in the treatment of pain and creating more access to opioids across the United States."

Did I read that correctly?

A Yes.

Q. And specifically, part of your opinion is that one of the ways that the paradigm shifted is that opioids became a first-line treatment for minor pain conditions and chronic pain conditions; is that right?

A Yes.

Q. As a result of that paradigm shifting in the treatment of pain it was generally accepted

medical practice to prescribe opioids to patients for chronic non-cancer pain, correct?

A Yes.

Q. Another result of the paradigm shift was that doctors prescribed opioids in higher doses as part of the generally accepted medical practice; is that right?

A Yes.

Q. And doctors, as part of generally accepted medical practice, also prescribed opioids on a longer term basis, correct?

A Yes.

Q. When we talk about generally accepted medical practice, that means that's one that most doctors at the time believed was the correct treatment option, correct?

A Yes.

Q. When we talk about generally accepted medical practice, that includes the State of New York, as well as the rest of the country; is that right?

A Yes.

Q. I'm going to ask you a little bit about something you were asked about this morning. Mr.

Hanly brought up something called the gateway effect; do you remember that this morning?

A Yes.

Q. You never used that specific phrase, gateway effect, or published that observation in any peer-review journal articles; have you?

A No.

Q. "No," you have not?

A I have not published that in any peer-review journal articles. I have used that in other contexts.

Q. Before you were hired as an expert witness in this case Mr. Hanly brought up a book that you wrote, Drug Dealer, M.D.

A Yes.

Q. And he noted that that book was from 2016, right?

A Yes.

Q. You worked hard on the book?

A Yes.

Q. Had to get your facts right?

A Pardon me?

Q. You tried to get your facts right as to what you included in the book?

A Yes, I did.

Q. So in that book, before you were hired by the Plaintiffs' lawyers here, you had concluded that the relationship between doctors' prescribing patterns and the initiation of heroin use remains unclear; is that right?

A Yes.

Q. In making that finding you cited to the New England Journal of Medicine, correct?

A Yes. But I believe I cited the wrong citation.

Q. Do you know what the right citation is?

A I can't recall it now, but I had intended to use something other than what I ended up using, which was a later publication.

Q. But the statement itself was included in your book, right?

A Yes.

Q. That is the relationship between doctors' prescribing patterns and the initiation of heroin use remains unclear?

A Yes. I had a very specific idea in mind with that that I didn't clarify, but I could, if you'd like me to.

Q. Dr. Lembke, did you or did you not write that the relationship between doctors' prescribing patterns and the initiation of heroin use remains unclear?

A Yes.

Q. I want to shift gears a little bit towards some of the marketing issues that you were asked about this morning.

A Okay.

Q. Can you identify any false or misleading claim about opioids made by a pharmaceutical distributor that's been named as a Defendant in this case?

A Yes, I can.

Q. Well, Dr. Lembke, I'd like to direct you to your New York deposition at page 70, line 14, and you were asked at the time the same exact question I just asked you, and that was can you identify any false or misleading claim about opioids that was made by a pharmaceutical distributor that has been named as a Defendant in this case, and you answered that question no.

Is that your testimony under oath?

A Yes. That was my testimony.

Q. And it was true at the time?

A At the time it was true.

Q. That testimony was given after you submitted your report in New York State, correct?

A Yes.

Q. You've not filed a supplemental report in New York State, the report you filed is the only report we have from you in New York State; is that right?

A That's correct.

Q. On page 6 of that report, I want to refer you to opinion 3. At opinion 3 you wrote: "The pharmaceutical opioid industry contributed to the paradigm shift in opioid prescribing through promotional materials and its use and manipulation of key opinion leaders, continuing medical education courses, professional medical societies, Federation of State Medical Boards, and the Joint Commission to convey misleading messages about the safety and effect -- and efficacy of prescription opioids."

Is that a correct reading of your opinion 3?

A Yes.

Q. So I would like to break that down and

just talk about the role of distributors or lack of role of distributors as to each of those, okay?

A Sure.

Q. When you say the pharmaceutical opioid industry used and manipulated key opinion leaders, you're not talking about distributors, correct?

A That's correct.

Q. When you say the pharmaceutical opioid industry used and manipulated continuing medical educational courses, you're not talking about distributors?

A No.

Q. "No," you're not talking about distributors?

A I'm not talking about distributors, no.

Q. When you say the pharmaceutical opioid industry used and manipulated professional medical societies, you're not talking about distributors there either; are you?

A No.

Q. When you say the pharmaceutical opioid industry used and manipulated the Federation of State Medical Boards and the Joint Commission there, you're not talking about distributors either; are

you?

A No.

THE COURT: You know, when a question calls for a yes or no, it might be a universal recommendation to have every witness watch the movie My Cousin Vinnie, when he is asked originally by a deputy he's told, You shot the sheriff. He says, I shot the sheriff. Then when the deputy gets on the stand, what did he say? He says, I shot the sheriff.

So when you say like no to that last question, you really mean something else. You've been doing a good job. You've been saying, No, I do not, or yes, I do. So for purposes of the record just --

THE WITNESS: Okay. Thank you. I've been worried to say more than yes or no.

THE COURT: All right. Am I the only person in this building that saw My Cousin Vinnie? Just curious. Let's go.

Q. Let's try to clean that up, if we could, because I think we understood what you were saying.

For each of those last five questions

that I asked you about distributors, your reference there did not include any action by distributors; is that correct?

A My reference there does not include any action by distributors, that is correct.

MR. PYSER: Thank you, Dr. Lembke, and thank you, your Honor, as well for helping clean up.

THE COURT: Is Mr. Carter -- he was referenced in a September 2nd letter as being an examiner; is that you, sir?

MR. CARTER: Yes, it is.

THE COURT: How are you?

MR. CARTER: I'm doing well. I have about ten minutes of questions, so if you would like me to proceed now, I can.

MR. PYSER: I'm sorry, your Honor, I wasn't quite done.

THE COURT: I heard you say "thank you," so that was my queue...

MR. PYSER: That was to my Cousin Vinnie reference there.

THE COURT: Mr. Carter, sit down and enjoy the show.

Go ahead.

Q. All right. As part of your methodology in this case, before serving your report, Dr. Lembke, did you consider any documents produced by Cardinal Health?

A No.

Q. Okay. And same question for AmerisourceBergen.

Before serving your report, did you consider any documents produced by AmerisourceBergen?

A No.

Q. As to McKesson Corporation, other than a single document that was brought up at your deposition, the Nucynta savings card, other than that single document, did you consider any other documents produced by McKesson?

A Not before submitting my report, no.

Q. As to that Nucynta document, you describe that document as a coupon or a savings card; is that right?

A That's correct, yes.

Q. So just talking generally about such documents, a savings card that offers co-pay

assistance for the cost of prescriptions, you understand that when a patient has a card for co-pay assistance, the patient still needs to obtain a prescription before they can obtain the medication; is that right?

A Yes, of course I understand that the patient still needs a prescription.

Q. And if a doctor has written a prescription, that means the doctor has made a decision that that particular medication is the appropriate medication for treatment of pain in that patient; is that right?

A That's harder for me to answer yes or no.

MR. PYSER: Bear with me one second, doctor.

Q. So presumably when a doctor has made a decision that a medication like Nucynta is an appropriate medication for acute treatment of pain in the patient and issues a prescription, that doctor has made a decision based on their own medical judgment, correct?

A Not entirely. There are other influences that are at play in a doctor's decision.

For example, if a drug rep came by and gave them a bunch of, you know, Nucynta saving cards and asked them to give them to patients, that would influence that decision.

Q. But the ultimate decision rather to prescribe or not, that decision rests with the doctor, correct?

A In the most superficial sense, yes.

Q. So you don't believe doctors have independent judgment that they exercise with their patients?

A Yes. But they can only base their judgment on the knowledge that they have, and if that's faulty knowledge, they can't exercise good judgment.

Q. Do doctors have an obligation to educate themselves?

A Yes, they do.

Q. As part of your methodology in this case, did you conduct your own analysis of psychiatric data, such as the ARCOS data, to reach a conclusion about distribution of opioids?

A No.

Q. As part of your report and your work

here, you're not able to point to any particular distribution of a particular medication and say that the prescriptions filled by a pharmacy as a result of that distribution were medically unnecessary; you can't get to that level of detail, can you?

A No, not to that level of detail.

Q. As part of your methodology you're not offering an opinion as to the appropriate number of pills that should have been distributed into the State of New York; are you?

A Probably I have offered an opinion on that topic, and I have stated before it should be at least four- or fivefold less than current prescribing.

Q. Beyond that four- or fivefold estimate, you're not putting forth a particular number of pills that you believe should have been distributed in the State of New York for particular medications; are you?

A Not a specific number, no.

Q. Same thing for Suffolk County and Nassau County. You're not offering an opinion as to the specific number of opioid medications that should have been distributed into Nassau or Suffolk County;

are you?

A I'm offering the same opinion for those counties as for the State of New York, as I said before.

Q. I'd like to draw your attention to another line in your report at page 18 this time. Do you have that in front of you?

A Yes. Let me just turn to it.

Q. This is something that was covered a little bit earlier. It's toward the top of the page, the Roman number III. It says: "The history of prescription opioid marketing distribution throughout the United States means that it's highly probable that prescribing rates in those counties were far lower in the 1990s before such marketing and distribution campaigns were implemented by the Defendants."

Do you see that?

A Yes.

Q. Okay. I want to just ask you a couple of questions about the basis for that statement.

Can you point to any report, article or analysis which concluded that the rate at which healthcare providers prescribed opioids increased

because pharmaceutical distributors shift prescription opioids to pharmacies?

A There are, as in my report, authoritative bodies who have weighed in on this, and I agree with them that the distribution of opioid pain pills is what contributed to the increased access to prescription pain pills, and access is a huge risk factor for misuse and addiction.

Q. I think maybe we're talking past each other.

What I'm asking you is whether there's a report, article or analysis which concluded the rate at which the healthcare providers prescribed, the prescribing decisions, are you aware of any analysis which concluded that healthcare providers' decisions to prescribe increased because pharmaceutical distributors shift prescription medicine to pharmacies?

A Well, I take it, as a matter of common sense, that you can't get the pills to the patients unless they're distributed to the pharmacies.

Q. I'm not asking about getting it to the patients, though, doctor. What I'm asking you is

about the healthcare providers' decision to write a prescription and whether you believe that the simple fact that a distributor shifted medication to a pharmacy caused a doctor to alter their medical judgment and write more prescription opioids?

A That's hard for me to answer yes or no because I -- my sense is it's a feed forward cycle. The more that were shift, the more patients became dependent on them, the more that doctors were in a position to have to continue to prescribe them.

Q. So sitting here today, can you point me to any academic article or study that found that doctors prescribing was based on the fact that distributors shift pills to pharmacies?

A Yeah, I'm not sure I really understand the point of the question, so it's hard for me to answer it.

Q. You can answer the question whether you understand the point of it or not.

So the question is: Are you aware of any study in which the authors of the study found that doctors prescribing increased because of the shifting by distributors of medicine to a pharmacy?

A The increased distribution meant that

these communities had more opioids, which meant that the general population had more access, either through legitimate prescription or otherwise, which then created the need for ongoing prescribing.

So I do think that it begins with the access and not with necessarily it's a feed forward cycle.

Q. Doctor, again, you're still not answering the question.

The question is pointed at doctors' prescribing decisions, healthcare providers' prescribing decisions, and the question is: Can you point me to a study in which the authors found that doctors' prescribing increased because distributors shift medication to a pharmacy?

THE COURT: Just a yes or no, doctor.

A No.

THE COURT: Next question.

Q. Dr. Lembke, I want to return to something you said this morning actually, this was point 2 of your summary.

And, Matt, if you could bring up point 2 of the summary.

So point 2 was opioid prescribing grows

fourfold starting in the 1990s, which increased the supply of potent and deadly opioids in the general population, including New York.

That was your point this morning, correct?

A Yes.

Q. And you were trying to be accurate when you testified this morning?

A Yes.

Q. You told the truth in your testimony?

A Yes.

Q. And here what you've said is that the prescribing increased the supply of opioids, correct?

A Yes.

MR. PYSER: You can take that down, Matt.

Q. Is it true that without a prescription, medication that shifts to a pharmacy will stay on the shelves of the pharmacy; is that right, doctor?

A Yes.

Q. Did you interview any pharmacists in the State of New York for purposes of forming your opinions in this case?

A No.

Q. Can you identify for the Court a specific doctor in Nassau or Suffolk County who prescribed more opioids because opioids were available at pharmacies?

A No.

Q. Can you identify a specific doctor in the State of New York who prescribed more opioids because opioids were available at pharmacies?

A No.

Q. As part of your professional practice as a doctor, before you prescribe a patient a medication do you regularly call the pharmacies in your area from which the patient could fill that prescription to see if the pharmacies have the medication you want to prescribe?

A Not usually.

Q. Dr. Lembke, do you agree with me that the large majority of opioid prescriptions written in New York were written for what the doctor who wrote them thought was a legitimate medical purpose?

A Yes.

Q. The number of pills of a particular medicine that a pharmacy dispenses is dependent on

the prescriptions written by healthcare professionals, true?

A Yes.

Q. Doctors have a responsibility to ensure that the medications they prescribe for patients are for a legitimate medical purpose, correct?

A Yes.

Q. Pharmacists can't dispense opioids without a prescription, right?

A Yes.

MR. PYSER: No further questions, your Honor.

THE COURT: Are you sure?

MR. PYSER: I'm sure this time.

THE COURT: Okay. We'll take 15 minutes. Thank you.

(WHEREUPON, a short recess was taken.)

THE COURT: Okay. I don't see the witness.

Welcome back.

THE WITNESS: Thank you.

THE COURT: Of course you're still under oath; you know that, correct?

THE WITNESS: What is that?

THE COURT: I said of course you're still under oath; you know that?

THE WITNESS: Yes, thank you.

THE COURT: Mr. Carter, you're up.

MR. CARTER: Thank you, your Honor.

EXAMINATION BY

MR. CARTER:

Q. Good afternoon, Dr. Lembke. We met at your deposition. My name is Ed Carter, and I represent Walmart, okay?

A Yes.

Q. I have just a few questions this afternoon, so hopefully it will move quickly.

You were asked some questions earlier today about some of the sources and individuals that you consulted in preparation for your report as part of your methodology, I want to start up to that topic in connection with your work in this case.

You did not interview any employees of Nassau County or Suffolk County; did you?

A No.

Q. You did not interview any law enforcement officers in the two counties; did you?

A No.

Q. You testified earlier about addiction and specifically opioid use disorder.

You cannot tell us which specific individuals or cases have opioid use disorder diagnosis in Nassau County; can you?

A No.

Q. Same question for Suffolk County?

A Same answer for Suffolk County.

Q. Likewise, you do not know the number of cases where a decedent in that Nassau County or Suffolk County was diagnosed with an opioid use disorder; do you?

A No.

THE COURT: You mean, "yes," that is correct?

THE WITNESS: That is correct.

MR. CARTER: Thank you, your Honor.

Q. Dr. Lembke, that is not something that you calculated as part of your methodology in this case; is it?

A No, that is not something that I have calculated.

Q. Likewise, you have not studied the overdose death records from either counties to

determine whether the individuals had a diagnosis of an opioid use disorder; did you?

A I did not look at whether they had a diagnosis of opioid use disorder.

Q. The methodology that you utilized in this case is not a methodology that is generally accepted by psychiatrists or diagnosee in opioid use disorder in a specific individual; is it?

A Can you rephrase the question?

Q. Sure.

The methodology you employed in this case to reach the nine opinions that were on the first slide that you showed today on direct, that is not an accepted methodology for diagnosing a patient in a clinical setting with an opioid use disorder; is it?

A Well, as part of forming my opinion I did use the methods for diagnosing opioid use disorder in individual patients, and my opinion is informed both by my clinical professional experience and the research that I did. So I did use that methodology.

I couldn't form an opinion about this topic unless I was able to apply the DSM criteria to

diagnosing an opioid use disorder.

Q. Maybe we're talking about two separate things.

You did not apply the DSM criteria to any patient in Nassau or Suffolk County or New York State; did you?

A No, I did not apply the DSM criteria to any specific patient, as you said.

Q. Thank you.

Now, if you were evaluating a patient in a clinical setting for a possible opioid use disorder diagnosis, you would consider the full context of information available to you in that clinical setting; wouldn't you?

A Yes.

Q. For example, you would consider the patient's medical history, including their mental health history, and any information regarding their history of substance abuse, fair?

A Yes.

Q. In a clinical setting you have never made a diagnosis of an opioid use disorder by disregarding that context and that clinical indication and instead relying exclusively on

aggregate epidemiological statistics, that's something you've never done in a clinical setting; is it?

A No.

Q. As part of your methodology you did not evaluate specific cases or specific individuals in Nassau County or Suffolk County to determine whether they ever had a prescription for an opioid medication that was made, distributed or dispensed by one of the Defendants; did you?

A No.

Q. As part of your work in this case, you described error in some of the documents that you considered, I want to follow-up on that topic, all right?

A Okay.

Q. Did you consider any documents produced from the files of a pharmacy Defendant in preparing your report for this case?

A Yes. -- oh, pharmacy Defendant, sorry -- well, after submitting this report I have reviewed some files like that, but not before submitting this report.

Q. Not for the Defendants in the New York

litigation, correct?

A Correct.

Q. Okay. And just to be clear, make sure we have it for the record, in preparing your report for this case, did you consider any documents produced from the files of a pharmacy Defendant?

A No, I did not consider documents produced from the files of a pharmacy Defendant for this report.

Q. As part of your work in this case, did you review the testimony or depositions of any employees or witnesses from a pharmacy Defendant?

A No.

Q. As part of your methodology in this case, did you study the details of the conduct of any pharmacy Defendant as it pertains to Nassau County or Suffolk County?

A No.

Q. Using Walmart, my client, as an example, did you study the details of Walmart distribution policies for controlled substances in Nassau or Suffolk County?

A No.

Q. Did you study the details of the

processes that Walmart put in place to empower its pharmacists to exercise their professional responsibility to evaluate prescriptions?

A No.

Q. Did you review any Walmart policies to identify a specific policy that you believe should have been changed?

A No.

Q. Did you identify any specific orders for opioids that a Walmart pharmacy placed that Walmart should have handled differently from a distribution perspective?

A No.

Q. Did you identify any specific prescriptions that Walmart should not have filled at its pharmacies?

A No.

Q. And if I asked you all of those questions for the other three pharmacy Defendants, would your answers be the same?

A My answers would be the same.

Q. Now I want to switch gears. You talked about marketing earlier. I want to ask you about that.

It's true that the pharmacy Defendants never marketed opioids; did they?

MR. HANLY: Objection to the form.

THE COURT: Time out. There's an objection. Mr. Carter, rephrase the question. Perhaps you should share your concept of marketing with the witness so we're on the same page.

MR. CARTER: Sure.

Q. In your report, when you offer opinions regarding marketing, have you offered any marketing opinions that pertain to the pharmacy Defendants?

A Not in my report.

Q. Okay. And as far as you're aware, did the pharmacy Defendants ever market opioids?

A Yes.

Q. Okay. I'd like to show you your deposition. It's the same one from the New York case that you looked at earlier today. Bear with me a moment while I get the screen.

THE COURT: What's the page and line, please.

MR. CARTER: The page and line is going to be 127, line 24, and I'm just trying to

get control so that I can present.

THE COURT: Okay.

Q. Are you able to see my screen with your transcript up, Dr. Lembke?

A Yes, I do. I see it.

Q. All right. So I want to direct your attention to the last page -- or, excuse me, the last line, down here at the bottom of the page:

"Are you aware of any marketing of opioids conducted by any of the retail chain pharmacy Defendants?"

And it goes to the next page.

"ANSWER: No."

Do you see that?

A Yes, I do.

Q. That's the testimony you provided under oath in your deposition in this case, correct?

A Yes. That was true at the time.

Q. That was true for purposes of your report in this case, correct?

A Yes.

Q. Since then you've never supplemented your report or put the pharmacy Defendants or anyone else on notice that there's been any change or

errata to your sworn deposition testimony, true?

A I can't speak to what Plaintiffs' counsel has notified Defendants about, but I have reviewed other records since then, which has led to my changing my opinion on this deposition question.

Q. But whatever your opinion is, that's not something you shared with anyone in New York, to your knowledge, true?

A Not in my report.

Q. You don't plan on testifying at trial in this case with respect to marketing by pharmacy Defendants, true?

A If I'm asked a question about whether or not pharmacies ever marketed specific products, to answer that truthfully I will have to say that I am aware of that having happened.

Q. We can deal with the representations of the various pleadings, I won't belabor the point, but in these subsequent materials that you reviewed, unrelated to New York and not in your New York report, do any of them relate to controlled substance prescription opioids?

A Yes.

Q. Do any of them relate to marketing in

Nassau or Suffolk County?

A Possibly, but there is no geographic specific information that I'm recalling.

Q. All right. And likewise, you cannot identify any claim about opioids made by a pharmacy Defendant that you allege was false or misleading; can you?

A Again, yes, I can, because I've reviewed other materials since the deposition and since my report.

Q. Let me pull up -- I'd like to direct you to page 127 of your deposition. Lines 20 to 23:

"Can you identify any false or misleading claim about opioids made by one of the retail pharmacy Defendants in this case?

ANSWER: No."

Do you see that?

A Yes, I do see that.

Q. That was the testimony that you provided under oath in your deposition in January, correct?

A Yes, that was the testimony I provided then.

Q. Between January and today, September 9th, have you issued an errata to correct your

testimony in the New York case?

A No.

Q. Have you issued a supplemental report to update your opinions in this case on that topic?

A No.

Q. In terms of the nine opinions that were listed on your first slide -- sorry, I'm having trouble with the mouse, your Honor, excuse my technical novice.

Back to my question, doctor.

The nine opinions that are listed on Slide 1 that you showed today, none of them relate to any marketing statements or allegedly misleading statements by the pharmacy Defendants, true?

A In my report I refer to the pharmaceutical opioid industry and in that I include the pharmacies.

Q. So is it your testimony that one of the nine opinions on Slide 1 references pharmacy Defendants making marketing statements?

A Yes.

Q. All right. I'd like to pull up Slide 1.

Which one of these statements references a pharmacy Defendant marketing opioids?

THE COURT: It's not on the screen.

MR. CARTER: That makes it harder, so let me --

THE COURT: Can somebody help out?

MR. CARTER: Your Honor, I relied on the shared Adobe, not the entire screen. So one second, I think I can fix this I believe.

THE COURT: Halfway there, Mr. Carter. You got the other one down.

MR. CARTER: Okay.

MR. CARTER: Is this one up now?

MR. HANLY: Yes.

Q. All right. So, Dr. Lembke, you do not have any references in Slide 1 to a pharmacy Defendant issuing a marketing statement, correct?

A That's true.

Q. Thank you.

And, in fact, if we go through your entire report for the New York case, it's also true that you do not mention any pharmacy Defendant by name at any location in your report, true?

A True.

Q. Likewise, your report does not identify any pharmacy Defendant as having, to a reasonable

degree of medical and scientific certainty, violated a regulation or duty of care in Nassau County or Suffolk County, correct, that's not anywhere in your report; is it?

A Correct. That's not in my report.

Q. Bottom line is, because you did not analyze or study the conduct of the pharmacy Defendants in Nassau and Suffolk County in preparation of your report, this case, you'll not be offering any opinion at trial regarding the specific conduct of a pharmacy Defendant in Nassau or Suffolk County; do you agree with that?

A Again, if I'm asked under oath to testify about the role of the pharmacies, I will offer an opinion that's based on additional material I've seen.

Q. But sitting here today, in terms of what's in your report, none of those opinions are articulated with specificity in your report for this case, true?

A That's true.

Q. Last topic. On direct you expressed an opinion that doctors were duped; do you recall that?

A Yes.

Q. I would like to follow-up on that.

If doctors were duped to the point where well-intentioned doctors genuinely believed that they were exercising appropriate medical judgment in prescribing opioids, you agree that the same phenomenon would also apply to pharmacists, fair?

A Yes. Possibly.

Q. In terms of your background and training, you are not familiar with the specific licensing requirements for pharmacists in New York; are you?

A No.

Q. You don't know what kind of training pharmacists in New York go through; do you?

A No, I don't.

Q. The education and training of pharmacists is not a topic that you've studied in connection for this case; is that correct?

A That is correct.

Q. You will not be offering an opinion at trial regarding what pharmacists in Nassau or Suffolk understood or believed about the risks and benefits of opioid medications; will you?

A No.

Q. You will not offer an opinion, starting from the specific pharmacists in those two counties, acted unreasonably in filling any specific prescription; will you?

A Not for any specific prescription, no.

Q. My final question. As part of your methodology in this case, you have not identified any particular case where specific prescriptions for opioids should not have been filled by a pharmacist acting in good faith; have you?

A Not any specific case, no.

MR. CARTER: Those are all the questions I have for you. Thank you.

THE WITNESS: You're welcome.

THE COURT: Mr. Hanly, redirect.

MR. HANLY: Thank you, your Honor.

REDIRECT EXAMINATION

MR. HANLY:

MR. HANLY: Could we take down that slide, please.

Q. Dr. Lembke --

A Yes.

Q. -- I'm going to ask you a few questions on redirect examination.

First of all, just to clarify, and perhaps I misheard or misunderstood one of the questions asked by Mr. Carter just a few minutes ago, the nine opinions that you hold and would give in this case at trial, if permitted to do so by Justice Garguilo, have nothing to do with the diagnosis or the diagnostic criteria for addiction, true?

A Well, yes and no. I mean, I, I must be familiar with those diagnostic criteria in order to have a working background knowledge of this problem more broadly.

Q. But there's nothing referred to in the nine opinions concerning any diagnostic criteria; is that right?

A Well, under opinion 1 addiction is a chronic illness. I do describe in brief what the diagnostic criterion are for diagnosing an opioid use disorder.

Q. There was a suggestion -- withdrawn.

Is there any peer-reviewed publication, guidelines, criteria, mandates, requirements of any sort that provide it is necessary to do widespread surveys of physicians in order to reach opinions,

for example, about the relationship between physicians' prescribing habits and, and consequent harms, is there any set of rules that say you have to do a survey of 10 or 100 or a thousand or a million doctors in order to have a sound basis upon which to make conclusions concerning the relationship, for example, between prescribing and ultimate harms?

A No, there are no mandated requirements or recommended requirements to that effect.

Q. You were asked a number of questions by Miss Strong concerning whether you are able to quantify the relative roles of different players, if you will, in the opioid saga in respect of the opioid epidemic, correct?

A Yes.

Q. All right. And -- but you already testified, before she asked you that litany of questions about your ability to give percentages, that you are not an econometrician, right?

A That's correct.

Q. You don't have any training in econometrics?

A That's correct.

Q. And your engagement in this case by the lawyers for the communities had nothing to do with you providing percentages of relative liability, correct?

A That's correct.

Q. Now, you testified, when asked a number of questions by Miss Strong about surveys, you answered on several occasions that you had done qualitative interviews; do you remember that?

A Yes.

Q. In fact, you did such interviews; is that correct?

A Yes, I did.

Q. There was a suggestion that, that was not disclosed and didn't appear anywhere in your report, correct?

A That was suggested, yes.

Q. Right. Do you have your report in the New York litigation handy?

A Yes, I do.

Q. Could you turn to page 5 of that report.

A Yes, I'm at page 5.

Q. Right. And up at the top is paragraph number 23; do you see that?

A Yes.

Q. And I'm just going to read the beginning part of that paragraph. You wrote: "In forming the opinions expressed in this report, I have relied on my medical training, more than 20 years of clinical experience, and my own research on opioid prescribing.

My research began circa 2001 and has been multimodal. I have done qualitative interviews with patients, providers and others in the healthcare field on questions related to opioid prescribing."

Did I read that correctly?

A Yes.

Q. That is, in fact, true; is it not?

A Yes.

Q. That while you did not do surveys of 10 or 100 or a thousand or a million doctors or patients, you did selective qualitative interviews of that very same population?

A Yes.

Q. Now, Miss Strong also took you through a number of risk factors for the development of opioid use disorder or addiction, right?

A Yes.

Q. But I don't recall her calling to your attention anything about dose and duration of the administration of opioids as constituting a risk factor.

My question to you is: Are dose and duration of the administration of these kinds of drugs a risk factor for the development of an addiction?

A Yes. The science showed that those are important risk factors for the development of addiction.

Q. Do you accept that science?

A Yes, I do.

Q. Okay. Is that concept generally accepted, that dose and duration -- in other words, how strong the pills are or how many you're taking and for how long are reflective or indicative of what your risk would be?

A Yes. Increasing dose and duration increase the risk of both addiction and overdose.

Q. You were asked questions about the FDA. I just want to ask you a couple of brief questions about that.

The FDA does not have laboratories where they do widespread testing of drugs; isn't that true?

A That's true.

Q. In fact, in determining whether a particular drug is safe and efficacious, the FDA has to rely upon information provided to it by what's called the response of the company that's making the drug, right?

A Yes.

Q. So there's a kind of a necessity on the part of the FDA to take at face value what is told to it concerning the results of any review of safety or efficacy?

MS. STRONG: Objection, your Honor.

This is Sabrina Strong again. I am trying to be very lenient with leading.

THE COURT: I got it.

MS. STRONG: Leading.

THE COURT: I'll sustain it. Rephrase the question.

MR. HANLY: Okay.

THE COURT: It's too suggestive of the answer.

MR. HANLY: Got it, Judge.

Q. The FDA does not do its own physical research on proposed new drugs, correct?

A That's correct.

Q. Where does the FDA get information then concerning the attributes of that proposed new drug or prospective indication for that new drug; where does that information come from?

A From the drug companies who are making the drug and trying to get approval for the drug.

Q. Now, there was a question asked by Mr. Pyser as to whether you used the term gateway effect in any peer-reviewed publication of yours, right?

A Yes.

Q. You testified that, no, that term did not appear in any such publication, but, of course, it does appear, in fact, it's part of the name of a chapter in your book, correct?

A That's true.

Q. All right. And isn't it also true that subsequent to the publication of your book in 2016 that at least one peer-reviewed report used the term gateway effect?

A Yes.

Q. And I'm just looking for that page, that slide that has that on it.

A I would say that gateway effect is a commonly accepted term in addiction medicine. It's not a new term or a creative term.

Q. But, in fact, in the year 2017, a year after the publication of your book, there was published a peer-reviewed article that actually references the gateway effect, right?

A Yes. Which article was that? Was that the Harbaugh?

Q. I believe it's Harbaugh, but I can't seem to find it.

But in any case, we can agree that subsequent to your use of the term gateway effect it was used by other medical researchers and authors, right?

A Yes.

MR. PYSER: Objection.

Leading again.

THE COURT: I'll allow it. Go ahead.

If we were going to hear an objection for every leading question, we'd be here until Thanksgiving.

Q. Okay. The report that I was referencing was Slide 18 that we looked at, doctor, and it's the NASEM report on pain management and the opioid epidemic.

We've called out this particular slide. We see that this paper was published in 2017, the year after your book in which you used the term gateway effect, and there we see a quote from the NASEM report. "Preponderance of evidence suggests that the major increase in prescription opioid use beginning in the late 1990s has served as a gateway to increased heroin use."

Did I read that correctly?

A Yes.

Q. You didn't write that; did you?

A No.

Q. You weren't part of the folks who wrote this consensus study report; were you?

A No.

Q. All right. Last area. Promise, your Honor.

Miss Strong's Slide Number 2 is, is the slide that consists of these circles with various things written in; do you remember that, doctor?

A The one with the big question mark in red at the end?

Q. Yes.

A Okay. Yes.

Q. Okay. And so let me see if I can use this. There we are. Okay.

And so Miss Strong labeled these Lembke's Factors, and let me see if I understand it.

Do you agree that these are some of the factors that in your opinion relate to the opioid epidemic?

A Yes, they are some of the factors.

Q. But they're not all of the factors; are they?

A No.

Q. Because what's missing from these -- this collection of circles of varying --

THE COURT: Mr. Hanly, ask the witness what's missing.

Q. What, if anything, are missing from these -- from this chart?

A Well, Miss Strong referred to other pharmaceutical companies by which I believe she meant those not involved in the litigation, so

that's a big circle that's missing.

What's also missing is key opinion leaders, drug detailers, drug rep detailers, the whole medical education paradigm shift that led doctors -- that doctors relied on to inform their prescribing.

Q. Should pharmaceutical manufactures be among these circles?

A Yes. So that's what I meant when I said not just other pharmaceutical companies, but the Defendants in this case should certainly be on this list.

Q. So -- well, I'm not going to lead you.

Who are the others that would be appropriately on the list of Dr. Lembke's Factors?

A So opioid manufacturers, opioid distributors, opioid pharmacies or pharmacies where opioids were dispensed and distributed.

MR. HANLY: Okay. Doctor, that is -- oh, one more area.

Q. Mr. Pyser brought to your attention a statement in your book in which, and I'm paraphrasing the statement, that prescription opioids, the relationship between prescription

opioids and heroin use is unclear; do you recall him asking you about that sentence?

A Yes, I do.

Q. That is a sentence that you wrote in your book?

A Yes.

Q. Can you explain to Justice Garguilo and all of us what you meant by that sentence.

A Yes. So at the time there was much debate about whether or not efforts that were being made at that time to curb opioid prescribing might be contributing to patients who had become dependent on and addicted on opioid, turning to elicit sources.

At the time that I published the book and finished my reference list there wasn't really good definitive data.

Furthermore, the natural history and the progression of the disease of addiction would lead patients who become addicted to prescription opioid to seek out more potent, more potent forms and more and cheaper sources, and as the U.S. population broadly became dependent on and addicted to prescription opioid the drug cartels responded to

that increased demand by making heroin more cheaply available.

Q. Again, this sentence, called to your attention by Mr. Pyser, was written in or around 2016?

A That's right. Actually, it was written probably a year before that. It takes about a year between finishing a manuscript and its coming out in publication, so I really finished the book in 2015.

Q. The NASEM article that we looked at that talked about a prescription opioid use as a gateway to heroin, increased heroin use, was two years or so after you wrote this sentence about the relationship being unclear?

A Yes, that's right.

Q. And does science progress over a two-year period?

A Yes. It became more clear right around that time period that, in fact, prescription opioid are a gateway to heroin.

MR. HANLY: Thank you very much, doctor. That's all I have. Thank you, your Honor.

THE COURT: Okay. Dr. Lembke, thank you very much.

THE WITNESS: Thank you.

THE COURT: You're excused.

THE WITNESS: Thank you.

THE COURT: With no other business, the Court will close the record.

Thank you all.

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C E R T I F I C A T I O N

I, Stephanie Casagrande Hague, CSR, RPR, an Official Court Reporter of the State of New York, County of Suffolk, do hereby certify that the above is a true and accurate transcription of my stenographic notes taken in the above-entitled action on this day;

Furthermore, photocopies made of this transcript by any party cannot be certified by me to be true and accurate.

Therefore, only those copies bearing an original signature in blue ink are official certified copies.

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STEPHANIE CASAGRANDE HAGUE, CSR, RPR
Official Court Reporter

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